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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

EMPOWER CLINIC SERVICES, L.L.C., *Plaintiff*, v. LEGITSCRIPT L.L.C., *Defendant*.	Case No. **COMPLAINT** **DEMAND FOR JURY TRIAL** **(REDACTED)**

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1. Plaintiff Empower Clinic Services, L.L.C., doing business as Empower Pharmacy, which is a Pharmacy Compounding Accreditation Board ("PCAB")-accredited 503A compounding pharmacy that makes personalized medications tailored to patients' individual needs pursuant to prescriptions, and Empower Pharma, which consists of two FDA-registered and current Good Manufacturing Practices ("cGMP") compliant 503B outsourcing facilities that compound products for healthcare provider in-office use (collectively, "Empower"), allege as follows by its undersigned attorneys:

OVERVIEW OF THE ACTION

2. This is an action for treble damages and permanent injunctive relief against LegitScript L.L.C. ("LegitScript") for violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2; the Texas Business & Commercial Code §§ 15.01-15.52 ("Texas Antitrust Act"); the New Jersey Antitrust Act, N.J.S.A. §§ 56:9-3, 9-4; and common law. In addition to treble damages, among other relief, this action seeks (i) an injunction prohibiting LegitScript from tortiously interfering with Empower's contracts, orders, and prospective economic advantage; (ii) an injunction prohibiting LegitScript from restraining customers from working with Empower; (iii) an injunction prohibiting LegitScript from commercially disparaging Empower; (iv) an injunction prohibiting LegitScript from tying its Healthcare Merchant Certification ("LegitScript Certification") to the purchase of products sold by entities that are certified by LegitScript; (v) an injunction prohibiting LegitScript from applying biased and discriminatory standards to Empower's applications for certification; and (vi) a declaration that LegitScript's exclusionary requirements and agreements prohibiting LegitScript applicants and certified entities from working with Empower pursuant to its anticompetitive "Affiliates" rule are null, void, and unenforceable.

3. In contrast to the majority of compounding pharmacies that are too small to present a competitive threat to traditional pharmaceutical manufacturers or their distributors, Empower Pharmacy is one of the only compounding pharmacies that has been licensed to sell compounded products in all 50 states and is PCAB-accredited. Empower has more than 1,000 employees and state-of-the-art facilities of more than 380,000 square feet. Due to Empower's scale, Empower is able to safely compound products at a volume greater than that of other, more regional, compounding pharmacies and outsourcing facilities. Empower thus plays an important role helping patients access personalized medicines when brand manufacturers' products contain allergens, dyes, or other ingredients that are unsafe or unsuitable for specific individuals; in improving and creating medications that are not commercially available and that prescribers determine could benefit their patients; and when brand manufacturers fail to fulfill consumer demand for medications during drug shortages.

4. Defendant LegitScript is a private, for-profit company that was initially founded in 2007 to verify the legitimacy of online pharmacies in response to what it described as a "proliferation of dangerous counterfeit pharmaceuticals sold on the internet." However, as LegitScript itself notes, its "offerings have grown and changed a lot since then." Today, without statutory authority to do so, LegitScript has arrogated to itself the claimed power to "weed out bad actors and their wares" from the market using its "database of problematic products" and a team of purported "investigative analysts." With only a few hundred employees, however, LegitScript lacks both the authority and practical ability to monitor and regulate the pharmaceutical marketplace in a fair and non-discriminatory manner and is instead influenced by entities seeking to restrain competition through the use of LegitScript's market and monopoly power.

5. In recent years, corresponding with increased demand for life-changing glucagon-like peptide 1 receptor agonists ("GLP-1") medications from compounding pharmacies as a result of the FDA listing such medications on its drug shortage list, LegitScript has introduced and enforced increasingly anticompetitive rules that are not reasonably necessary or narrowly tailored to achieve any procompetitive justification. Over the course of the last few years, LegitScript has increasingly disparaged Empower to its customers and aggressively coerced Empower's customers applying for LegitScript Certification to agree to stop doing business with Empower on the basis that Empower is not itself LegitScript-certified. Despite the fact that these customers had chosen to purchase from Empower based on the merits of competition and Empower's quality, pricing, and services, LegitScript demanded that customers concertedly refuse to deal with Empower because LegitScript does "not allow" any "certified clients to work with Empower Pharmacy."

6. In doing so, LegitScript has orchestrated an unlawful and anticompetitive group boycott or "concerted refusal to deal" against Empower that violates state and federal antitrust laws, has tortiously interfered with Empower's contractual and business relations, has tied its certification to the purchase of products from LegitScript-certified entities, and has commercially disparaged Empower. LegitScript's recent rule changes and aggressive campaign against Empower make no economic sense for an independent certifying entity but for an unlawful agreement to disadvantage Empower to the benefit of one or more of Empower's competitors. Indeed, LegitScript enforces its anticompetitive and exclusionary rules in a biased, arbitrary, and capricious way by turning a blind eye to LegitScript-certified entities that violate its rules by purchasing products from entities that are not LegitScript-certified when they are purchasing from entities other than Empower, such as from powerful brand manufacturers.

7. LegitScript has also repeatedly declined to grant Empower LegitScript Certification to certify it as a "legitimate" pharmacy despite Empower's demonstrated efforts towards maintaining compliance with the FDA and State Boards of Pharmacy. In contrast, LegitScript has certified, and declined to revoke the certification of, pharmacies that have pled guilty to serious violations of law for intentionally selling unapproved drugs or that have faced serious regulatory enforcement actions, including as a result of patients dying. LegitScript's blatantly discriminatory treatment of Empower compared to other pharmacies supports the conclusion that LegitScript has competitively disadvantaged Empower to the benefit of LegitScript-certified entities and other Empower competitors with which LegitScript has close ties. As one example, LegitScript imposed an atypical and arbitrary waiting period on Empower, precluding it from applying for certification for a period of time that just so happened to correspond with the time needed for a large pharmaceutical competitor with close ties to LegitScript to remove its GLP-1 medication from the FDA shortage list. LegitScript has thus applied its certification standards in a biased and arbitrary manner that has an anticompetitive effect.

8. As one nonprofit organization has noted, "Americans pay by far the highest prices in the world for most prescription drugs, and of course big pharma would like to keep it that way." To that end, the nonprofit reported that "[b]ig pharma is a major proponent" of "Shadow Regulation" to impose terms of service addressing pharmaceutical sales in a similar way, noting, "You might assume that the various terms of service of these companies, although all addressing online pharmaceutical sales in a similar way, were devised independently and voluntarily. But that isn't the case." The nonprofit specifically identified LegitScript as the entity that "carries out most of the operational level arrangements that are agreed at a level of principle" by a "confusing web of similar sounding organizations with overlapping memberships, such as the

Alliance for Safe Online Pharmacies (ASOP) and the Center for Safe Internet Pharmacies (CSIP)," the former of which is composed of pharmaceutical industry competitors and the second of internet platforms. As the nonprofit reported, LegitScript "was instrumental in the formation of both ASOP and CSIP." The nonprofit further reported that "such private deals" have been used to "block" pharmacies from essential internet intermediaries needed to compete. "The unsurprising result is that the measures put in place by this closed and captured process are too broad, favoring the private interests of big pharma, limiting access to information and access to safe and affordable medicine."[1]

9. Years of anticompetitive conduct by LegitScript—including: (i) biased and disparate treatment of Empower; (ii) the expanded interpretation and enforcement over time of an anticompetitive "Affiliates" rule used to block LegitScript applicants and certified members from purchasing from Empower; (iii) misleading and disparaging statements targeting Empower; (iv) preferential treatment of ASOP members and LegitScript-certified entities; and (v) reporting that LegitScript carries out agreements reached with ASOP members through its business—all provide evidence that LegitScript has not only entered into unreasonable restraints of trade by organizing a group boycott of customers against Empower but has further done so as a result of an unlawful agreement with one or more Empower competitors.

10. Far from merely "weed[ing] out bad actors" and counterfeit pharmaceuticals, LegitScript now wields its power to restrain competition for the sale of legitimate pharmaceuticals sold by entities such as Empower that are duly authorized to sell its compounded

[1] Jeremy Malcolm, *How Big Pharma's Shadow Regulation Censors the Internet*, Elec. Frontier Found. (Oct. 6, 2016), https://www.eff.org/deeplinks/2016/09/how-big-pharmas-shadow-regulation-censors-internet. Electronic Frontier Foundation is rated "[h]igh for factual reporting due to proper sourcing and a clean fact-check record" with "HIGH CREDIBILITY" by Media Bias/Fact Check. *See* https://mediabiasfactcheck.com/frontier-media-bias-credibility-rating/.

products by the state and federal governmental bodies that hold the actual authority to regulate pharmaceutical markets in the United States. LegitScript's Healthcare Merchant Certification program purports to distinguish between "'rogue' internet pharmacies" that "expose consumers to danger" and are "operating with flagrant disregard for the law" from "legitimate pharmacies trying to reach patients in need." Its website prompts visitors to "enter a website to see if it is LegitScript-certified, legitimate, or rogue," suggesting that legitimate pharmacies that are not approved by LegitScript are instead illegitimate or rogue merely because they are not approved by this private entity that has sought to entitle itself to regulate pharmaceutical markets. Far from accurately identifying safe pharmacies, LegitScript's failure to adopt and apply neutral standards in an unbiased way and failure to resist the anticompetitive pressures of Empower's competitors have instead unreasonably restrained free and fair competition among legitimate pharmacies that are in fact seeking to reach patients in need.

11. While LegitScript is small in size, it has amassed and exercised monopoly power in the market for certification and substantial market power in the supply of internet advertising to online pharmacies as a result of a web of agreements it has entered into with major internet platforms pursuant to which they agree not to permit advertisements by online pharmacies unless accredited by LegitScript. Empower's customers cannot risk either losing their LegitScript Certification or not obtaining LegitScript Certification because that would severely restrict, if not altogether eliminate, their ability to advertise to consumers over the internet. As LegitScript has noted, without certification, "many banks, advertising programs, social media platforms, and ecommerce websites will terminate your account."

12. As LegitScript recognizes, "Search engines and social media platforms"—the majority of which require a LegitScript Certification to serve ads—"are where patients search

for healthcare providers."[2] That said, it is crucial that patients have an unbiased way to identify and access safe, legitimate compounding pharmacies. While LegitScript purports to fulfill this role, in reality, as LegitScript's history of certifying some pharmacies with serious regulatory violations while denying certification to others with far less severe regulatory issues shows, LegitScript has used its market power to restrain competition from competitors of LegitScript-certified entities and other competitors with which LegitScript has close ties. LegitScript has unreasonably and unjustifiably restrained Empower's customers and their patients from accessing additional and lower-priced compounded products they otherwise would have purchased in a free and fair, competitive market. Notably, as discussed below, Empower was not only "ready and willing" to apply for its own certification, but repeatedly sought certification only to be denied certification based on pretextual and discriminatory interpretations of LegitScript's standards.

13. LegitScript has harmed the competitive process by restraining competition on the merits for sales to LegitScript-certified entities and applicants at the better prices and quality that would otherwise prevail in a competitive market. By blocking sales to its certified entities and applicants, LegitScript has further restrained competition on the merits for certification by forcing entities to seek certification from LegitScript when they would have preferred to obtain certification, or have already obtained certification, from another accreditation organization that is not a for-profit company implementing a sham standard while seeking to insert itself as a private gatekeeper of already regulated markets. Certifications offered by LegitScript's

[2] Certification, LegitScript https://www.legitscript.com/certification/healthcare-certification/ (last visited Mar. 22, 2025).

competitors lose their value if those certifications cannot be used to increase, or even to maintain, the sales made by certified customers.

14. LegitScript's unlawful and anticompetitive conduct has harmed Empower, Empower's customers, its patients, and LegitScript's competitors and continues to harm them to this day. LegitScript's conduct has become even more egregious during the time of a national shortage of life-changing GLP-1 medications needed to treat conditions such as diabetes and obesity. LegitScript's anticompetitive scheme restraining Empower and others from fully participating in the market for the supply of GLP-1 medications in a time of a national shortage has reduced the output of GLP-1 medications and restrained the sale of lower-priced GLP-1s and other products, thereby causing actual adverse effects by making it harder for patients to gain access to the medications they need.

15. LegitScript's conduct restraining sales of safely compounded medications also made it harder for patients to financially access much-needed medications. For example, patients have been losing coverage for GLP-1 medications as insurers choose not to cover expensive brand-name medications and, unsurprisingly, many cannot afford to pay over $1,000 a month out of pocket for brand-name GLP-1s. Empower's prices for compounded GLP-1s are typically a fraction of the price of branded GLP-1s and are also often lower priced even compared to other compounding competitors. Thus, customers and patients forced to purchase different products as a result of LegitScript blocking sales of Empower's compounded products have not only had to scramble to find an alternative supply but have often had to pay substantially more as a result.

16. As detailed below, LegitScript has violated the law in multiple ways, including by (i) orchestrating an unlawful group boycott or "concerted refusal to deal" among LegitScript-certified entities and applicants unreasonably restraining them from purchasing

products from Empower that customers otherwise would have purchased in a competitive market; (ii) tying and conditioning access to the LegitScript's Healthcare Merchant Certification on applicants' agreement to only purchase products from LegitScript-certified entities and specifically not to purchase products from Empower; (iii) commercially disparaging Empower based on false and misleading information; (iv) denying Empower certification based on the biased and discriminatory application of standards or rules from which LegitScript exempts Empower's competitors; and (v) tortiously interfering with Empower's relationships with customers that had informed LegitScript of supply agreements and relationships with Empower.

THE PARTIES

17. Plaintiff Empower Clinic Services, L.L.C. is organized under the corporate laws of the State of Texas and has its principal place of business in Houston, Texas. Empower's headquarters is located at 7601 North Sam Houston Parkway, Suite 100, Houston, Texas 77064. Empower was founded in 2008 by Shaun Noorian and has expanded its operations across North America to provide access to quality, personalized, and affordable medication. Empower operates a 503A compounding pharmacy, an FDA-registered and cGMP-compliant outsourcing facility in Texas, and has established another FDA-registered and cGMP-compliant outsourcing facility in New Jersey. Empower offers both sterile and non-sterile compounded products to individual patients based on prescriptions submitted by their healthcare providers. Plaintiff Empower Clinic Services, L.L.C. does business as Empower Pharmacy to operate as a 503A compounding pharmacy, which specializes in creating patient-specific medications tailored to individual needs. Plaintiff Empower Clinic Services, L.L.C. also does business as Empower Pharma, an FDA-registered 503B outsourcing facility engaged in the business of sterile and non-sterile pharmaceutical preparations for weight management, hormone replacement therapy,

intravenous nutrition, mental health, skin care, sexual dysfunction, fertility, men's health, and women's health; and pharmaceutical preparations for the prevention, reduction, and treatment of cardiovascular, lymphatic, respiratory, pulmonary, neurological, renal, gastrointestinal, musculoskeletal, dermatological, allergic, inflammatory, autoimmune, gynecological, genetic, longevity, metabolic, and pain conditions. Empower Pharma operates a 503B facility in Houston, Texas, and has established its newest 503B facility in East Windsor, New Jersey.

18. Defendant LegitScript L.L.C. is organized under the corporate laws of the State of Oregon and has its principal place of business in the State of Oregon. LegitScript, founded by John Horton, is a for-profit, privately managed verification and monitoring service for online and other pharmacies and has been seeking to expand to other areas as well.

ADDITIONAL AGENTS AND CO-CONSPIRATORS

19. Various persons and entities who are not named as Defendants have participated as co-conspirators in the violations alleged herein and have performed acts and made statements in furtherance thereof. These other individuals and entities have facilitated, adhered to, participated in, and/or communicated with others regarding LegitScript's unlawful activities. Plaintiff reserves the right to name some or all of these entities as defendants at a later date.

JURISDICTION AND VENUE

20. This action arises, in part, under Section 16 of the Clayton Act, 15 U.S.C. § 26, to prevent and restrain violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2; and under Section 4 of the Clayton Act, 15 U.S.C. § 15, to compensate Plaintiff for its damages.

21. This Court has jurisdiction over the federal law claims alleged herein pursuant to 15 U.S.C. § 15 and 28 U.S.C. §§ 1331, 1337. This Court also has subject matter jurisdiction

over all claims pursuant to 28 U.S.C. § 1332(a)(1). The parties are citizens of different states, and the matter in controversy exceeds $75,000.

22. This action arises, in part, under the Texas Antitrust Act, Texas Business and Commercial Code §§ 15.05(a) and 15.05(b), the New Jersey Antitrust Act, N.J.S.A §§ 56:9-3, 9-4, and Texas and New Jersey common law. This Court has supplemental jurisdiction over Empower's claims arising under these laws pursuant to 28 U.S.C. § 1367 because the facts alleged herein support claims under both federal and state law.

23. This Court has personal jurisdiction over Defendant LegitScript pursuant to Section 12 of the Clayton Act, 15 U.S.C. § 22, because LegitScript may be found or transacts business in Oregon, as demonstrated by its state of incorporation. In light of LegitScript's presence in Oregon, the exercise of jurisdiction over LegitScript would not offend traditional notions of fair play and substantial justice. Further, LegitScript's unlawful conduct alleged herein has impacted and restricted pharmacies' and patients' access to compounded products in Oregon, and the effects of LegitScript's unlawful conduct has been felt by pharmaceutical customers and patients in this district.

24. Venue is proper in this district pursuant to Section 12 of the Clayton Act, 15 U.S.C. § 22 because the domestic entity Defendant is incorporated within this district and has its principal place of business in this district. Additionally, LegitScript maintains an active presence in the district, having accredited and continuing to maintain and renew accreditations for pharmacies in the State of Oregon.

REGULATORY BACKGROUND

I. Regulation of Compounding Organizations in the United States

25. Per the United States Food and Drug Administration ("FDA"), drug compounding is "a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[3]

26. Compounding organizations are subject to multiple layers of laws and regulations including but not limited to, sections of the Food, Drug, and Cosmetics Act ("FD&C Act"), state statutes and regulations governing pharmacies, and controlled substance regulations.

27. In the United States, compounding organizations are separated into two designations: 503A and 503B, each corresponding with sections of the FD&C Act. Pharmacies classified under section 503A of the FD&C Act (21 U.S.C. § 353a) are those that compound products for specific patients whose prescriptions are sent by their healthcare provider. Meanwhile, outsourcing facilities classified under section 503B of the FD&C Act (21 U.S.C. § 353b) are those that compound products on a larger scale (or bulk amounts) for healthcare providers to have on hand and administer to patients in their offices.

28. Section 503A of the FD&C Act (21 U.S.C. § 353a) also describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a state-licensed pharmacy or federal facility, or by a licensed physician, to be exempted from FD&C Act sections on FDA approval prior to marketing, cGMP requirements, and labeling with

[3] U.S. Food & Drug Admin., *Human Drug Compounding*, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (last visited Mar. 22, 2025).

adequate directions for use.[4] Additionally, 503A pharmacies are also regulated by state boards of pharmacies and adhere to certain United States Pharmacopeia ("USP") standards[5]—specifically, USP 797 (pharmaceutical compounding – sterile preparations), 795 (pharmaceutical compounding – nonsterile preparations), and 800 (hazardous drugs – handling in healthcare settings).

29. In 2013, Section 503B of the FD&C Act (21 U.S.C. § 353b) was signed into law, creating a new category of compounders known as "outsourcing facilities." Section 503B outsourcing facilities are subject to cGMP requirements and are permitted to distribute compounded drugs either pursuant to a patient-specific prescription or in response to an order from a health care provider (e.g., a hospital).

30. The FDA uses a variety of means to ensure that compounding organizations comply with regulations and are adhering to safe practices when manufacturing products. The main regulatory standard for ensuring pharmaceutical quality is the Current Good Manufacturing Practice or cGMP. Enforced by the FDA, cGMP provides for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. As stated, the FDA requires 503B outsourcing facilities to be cGMP-compliant. To be cGMP-compliant, a 503B outsourcing

[4] Section 503A requires that all drugs be compounded by a licensed physician or pharmacist; compounded drugs must be for identified individual patient use based on the receipt of a valid prescription issued by a medical provider, or such drugs must be prepared in anticipation of the receipt of such a prescription, provided that there is a patient-physician history between the prescriber and the pharmacist and other conditions are met. *See* 21 U.S.C. § 353a. If satisfied, the compounded drug product is exempted from three sections of the FD&C Act: (1) section 501(a)(2)(B) concerning cGMP requirements; (2) section 502(f)(1) concerning the labeling of drugs with adequate directions for use; and (3) section 505 concerning approval of drugs under new drugs applications or abbreviated new drug applications.

[5] USP is an independent, nonprofit organization that develops and promulgates certain standards applicable to the pharmaceutical industry. *See* USP Ref. Standards, U.S. Pharmacopeia, https://www.usp.org/reference-standards (last visited Mar. 22, 2025).

facility must establish strong quality management systems, obtain appropriate quality raw materials, establish robust operating procedures, have the ability to detect and investigate product quality deviations, and maintain reliable testing laboratories. [6]

31. Compounders at FDA-registered 503A pharmacies and 503B outsourcing facilities may use bulk drug substances, also known as active pharmaceutical ingredients ("API"), in the compounding process. Sections 503A and 503B of the FD&C Act limit the types of bulk drug substances that can be used in compounding. In general, adding drugs to a bulk drug list means that pharmacies can use those drugs as active ingredients in compounded medications so long as other conditions are also met. The FDA maintains separate bulk substances lists for 503A pharmacies (the "503A Bulk Drug Substances List") and 503B outsourcing facilities (the "503B Bulk Drug Substances List").

32. The FDA also maintains a drug shortages list.[7] The FDA defines a drug shortage as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug."[8] The FDA tracks shortages at the national level and receives information from manufacturers about their ability to supply the market. The FDA considers a drug to be in shortage when, on a nationwide level, supply is not meeting current demand, or if supply is not forecasted to meet projected demand.

33. Section 503A of the FD&C Act restricts compounding of drugs that are "essentially

[6] U.S. Food & Drug Admin., *Facts About the Current Good Manufacturing Practice (CGMP)*, https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp (last visited Mar. 22, 2025).
[7] U.S. Food & Drug Admin., *FDA Drug Shortages*, https://dps.fda.gov/drugshortages (last visited Mar. 22, 2025).
[8] U.S. Food & Drug Admin., *Frequently Asked Questions about Drug Shortages*, https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages.

copies of commercially available drugs."[9] Nonetheless, compounders operating under section 503A are not banned entirely from compounding drugs that are essentially copies. Under Section 503A, compounders operating under this section of the FD&C Act may compound certain amounts of drugs that are essentially copies so long as the compounding is not done "regularly or in inordinate amounts." 21 U.S.C. § 353a. However, when the FDA determines that a certain drug is not commercially available and is added to the FDA's drug shortages list, the limitation on 503A pharmacies' ability to compound essentially copies is temporarily suspended.

34. Moreover, specifically for compounders classified as 503A pharmacies, a compounded drug is not considered to be an "essential copy" of an FDA-approved drug if it is altered specifically (i.e., tailored) for an identified patient and provides for that patient a "significant difference, as determined by the prescribing petitioner, between the compounded drug and the comparable commercially available drug." *See* 21 U.S.C. § 353a(b)(2). Thus, in line with the purpose of 503A pharmacies, such compounders may compound and dispense drugs according to prescriptions specific to particular patients without regard to frequency or amount limitations described in 21 U.S.C. § 353a(b)(1)(D), § 353a(b)(2).

35. In contrast, 503B outsourcing facilities are ordinarily prohibited from compounding essentially copies of FDA-approved drugs in any amount (21 U.S.C. § 353b) unless there is a change that produces a "clinical difference" for the patient, as indicated by the provider and documented on the prescription. 21 U.S.C. § 353b(d)(2)(B). However, when the FDA places a drug on its shortages list, the restriction on 503B outsourcing facilities' ability to compound

[9] The FDA considers a compounded drug product to be "essentially a copy of a commercially available drug product" if the compounded drug has the same active pharmaceutical ingredient(s) ("APIs") as the commercially available drug product; the APIs have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug.

essentially copies is temporarily suspended. Once a drug is added to the FDA shortages list, 503B outsourcing facilities may use bulk drug substances (APIs) to compound that drug.

36. As mentioned, like 503A pharmacies, the FD&C Act does allow for 503B outsourcing facilities to compound drugs using the active ingredients in an FDA-approved drug not included on the 503B Bulk Drug Substances List if "there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug." 21 U.S.C. § 353b(d)(2)(B). Thus, 503B outsourcing facilities may also compound specifically-altered drugs in limited circumstances.

37. Altogether, when shortages in a particular FDA-approved drug exist, compounding pharmacies and outsourcing facilities are legally permitted to produce and distribute their own copies of the medications at issue. And, in instances when a patient has a demonstrated need for a specifically altered drug that produces for an individual patient a clinical difference, as determined by a prescribing practitioner, between the compounded drug and the comparable approved drug, both 503A pharmacies and 503B outsourcing facilities are permitted by statute to compound the drug at issue.

II. Relevant FDA Proposed Rules and Draft Guidelines

38. The FDA, most often through notice-and-comment rulemaking, has submitted proposed rules affecting the day-to-day operations of 503A compounding pharmacies and 503B outsourcing facilities in the period during which LegitScript carried out its unlawful conduct against Empower.

39. One such proposed rule pertains to "Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the

Federal Food, Drug, and Cosmetic Act." *See* 89 Fed. Reg. 19776 (proposed Mar. 20, 2024) (to be codified at 21 C.F.R. pt. 216).

40. As a baseline, outsourcing facilities classified under 503B and compounding pharmacies classified under 503A are prohibited from compounding drugs that have been identified "directly or as a part of a category of drugs … on a list published by the Secretary … of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into the account the risks and benefits to patients." 21 U.S.C. § 353B(a)(6)(A).

41. By statute, a drug product may not be compounded by a 503A pharmacy if it has been "identified by the Secretary or regulation as a drug that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product." 21 U.S.C § 353a(b)(3)(A).

42. Also by statute, a drug product may not be compounded by a 503B outsourcing facility if it has been "identified (directly or as part of a category of drugs) on a list published by the Secretary … of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients." 21 U.S.C. § 353B(a)(6).

43. To this end, on or around March 20, 2024, the FDA proposed a rule establishing criteria for listing drug products or categories of drug products that present demonstrable difficulties for compounding—i.e., "Demonstrable Difficulties for Compounding Lists" ("DDC

Lists").[10] Pursuant to the FDA's proposal, the Agency would create and maintain lists of drug products or categories of drug products that cannot be compounded because they present demonstrable difficulties for compounding (*see* 21 U.S.C. §§ 353a-b); the FDA would create and maintain two separate lists: one for compounders covered by 503A, and one for outsourcing facilities covered by 503B. The FDA has also proposed six (6) criteria it would use to assess whether a drug product or categories of drug products should be added to its DDC Lists. Moreover, the FDA has identified three (3) categories of drug products it proposes to include on the DDC Lists. Under the FDA's proposed rule, once added to a DDC List, these drug products or categories of drug products, if compounded, would not qualify for the exemptions from the provisions of the FD&C Act discussed previously. In other words, "[d]rug products or categories of drug products that appear on the DDC Lists … may not be compounded under either section 503A or section 503B, respectively." As of March 11, 2025, this proposed rule has not yet been finalized.

44. From time to time, the FDA will also publish draft guidance pursuant to 21 C.F.R. 10.115(b). While these guidance documents do not establish legally enforceable responsibilities and thus are not binding on the FDA or the public, they do describe the Agency's current thinking on a topic and are typically viewed only as recommendations (non-binding), unless specific regulatory or statutory requirements are cited.

45. Relevant to the facts of this Complaint is an FDA draft guidance published and distributed on around June 28, 2023 entitled: "Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry." U.S. Food & Drug Admin.,

[10] *See* Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, 89 Fed. Reg. 19776 (proposed Mar. 20, 2024) (to be codified at 21 C.F.R. pt. 216).

Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry: Draft Guidance (2023) ("Draft Guidance on Wholesaling").

46. Under section 503B of the FD&C Act, one of the conditions that must be met for a drug compounded by an outsourcing facility to qualify for the exemptions in section 503B of the FD&C Act is that the drug "will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug." 21 U.S.C. § 353(b)(A)(8). This rule limiting to whom 503B outsourcing facilities may sell or transfer[11] their compounded drug products is known as the "prohibition on wholesaling." The FD&C Act, however, "does not prohibit the administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1) [21 U.S.C. § 353(b)(1)]." *Id.*

47. On or around June 28, 2023, the FDA published its Draft Guidance on Wholesaling explaining its current thinking on the prohibition on wholesaling. The FDA explained that it "interprets this provision to mean that a drug compounded by an outsourcing facility may be eligible for the exemptions in section 503B of the FD&C Act where the drug is distributed directly from an outsourcing facility to a health care facility, such as a hospital or clinic, where the drug is administered to a patient, or to a State-licensed pharmacy or Federal facility where the drug is dispensed pursuant to a prescription executed in accordance with section 503(b)(1) of the FD&C Act." *Id.* at 6, 9 (emphases added). This language has been interpreted to mean that a 503B outsourcing facility may supply medications to a state-licensed 503A pharmacy

[11] Per FDA interpretation, the phrase "'sold or transferred by an entity other than the outsourcing facility,' as used in section 503B(a)(8) of the FD&C Act, encompasses instances when an entity other than the outsourcing facility that compounded a drug has sold or transferred the drug. Transfers, for purposes of this provision, encompass movements of the drug from one entity to another, regardless of whether the drug was sold as part of the transfer." *Draft Guidance on Wholesaling* at 4.

which dispenses the drug directly to a patient pursuant to a valid prescription. Accordingly, the express language in the FDA's Draft Guidance on Wholesaling opened the door to increased partnerships between 503A state-licensed pharmacies or federal facilities and 503B outsourcing facilities.

III. FDA Form 483s and Warning Letters

48. To assess compliance with cGMP standards, adequacy of the manufacturing processes, and quality of facilities' products on the market, the FDA routinely performs surveillance inspections for 503B facilities. While the FDA typically defers to state officials to inspect 503A state-licensed pharmacies, the FDA may choose to conduct an inspection, with or without the involvement of state investigators.

49. After an inspection, the FDA may issue an FDA Form 483 ("Form 483"), which details a series of observations from an investigator(s) on any conditions that, in their judgment, *may* constitute violations of the FD&C Act, cGMP standards, and related Acts, or otherwise indicate a drug consists in part of any filthy substance or has been packed in an unsanitary condition or the like.[12] ***The Form 483, however, "does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any of its relevant regulations."***[13] The recipient of a Form 483 is encouraged to respond in fifteen days explaining how the entity that was subject to inspection plans to correct the findings from an inspection. The firm may also raise disagreements with the inspector's observations and detail the reasons it believes that the findings in the Form 483 were unwarranted.

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[12] *See* Section 704(b) of the FD&C Act, 21 U.S.C. § 374.

[13] U.S. Food & Drug Admin., *FDA Form 483 Frequently Asked Questions,* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last visited Mar. 22, 2025) (emphasis added).

50. A firm's response to an FDA Form 483 triggers one of two outcomes: either the response is satisfactory and the matters are deemed resolved, or the response is insufficient and a Warning Letter or, if more serious, other enforcement action will ensue. The FDA may—*but is not required to*—send a closeout letter or Establishment Inspection Report ("EIR") to acknowledge it received the recipient's response and deem the matters resolved, but this confirmation is not guaranteed.[14]

51. Warning Letters are more official notices that could include concerns such as poor manufacturing practices, problems with claims for what a product can do, or incorrect directions for use. However, even a Warning Letter is "informal and advisory" and communicates the agency's position on a matter, but it does not commit FDA to [take] enforcement action."[15] Thus, like a Form 483, the "FDA does not consider Warning Letters to be final agency action on which [the FDA] can be sued."[16]

52. Like a Form 483, a Warning Letter provides the recipient an opportunity to address the FDA's concerns and requires a response. Responses can consist of correction plans, which the FDA reviews and ensures are adequate. Recipients that disagree with the FDA's basis for its concerns can choose to supply the FDA with its reasoning and supporting information. The FDA instructs that "[m]atters described in the FDA warning letters may have been subject to

[14] *See* U.S. Food & Drug Admin., *About Warning and Close-Out Ltrs.*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters, (last visited Mar. 22, 2025) ("FDA ***may issue*** a Warning Letter close-out letter … once the Agency has completed an evaluation of corrective actions undertaken by a firm in response to a Warning Letter[.]") (emphasis added).
[15] Advisory Actions, 4-1 FDA Regulatory Procedures Manual, July 2024.
[16] *Id*.

subsequent interaction between FDA and the letter recipient that may have changed the regulatory status of issues letter."[17]

53. The FDA is not required to "close-out" a Form 483 or a Warning Letter. After issuing a Form 483, the FDA can elect to take no further action and there is no timeline in which the FDA must make a final decision.[18] Pursuant to this process, a final decision can, therefore, be pending indefinitely.[19] LegitScript has accordingly certified entities that have received Form 483s and Warning Letters.

54. Neither the Form 483 nor Warning Letter constitute a regulatory violation. As described above, the Form 483 sets out inspection observations and the Warning Letter sets out the FDA's observations and conclusions which require remedial action or a response. The Form 483 and Warning Letter are not dispositive as to whether the pharmacy's actions have violated the FD&C Act or otherwise, and the FDA may simply decide not to take any action to close out a Form 483 and Warning Letters.

IV. The FDA Adds Injectable GLP-1 Medications to its Drug Shortages List

55. GLP-1 drugs are a class of medications that mimic the action of the glucagon-like peptide-1 hormone, which is involved in the regulation of blood sugar levels. For a number of years, GLP-1 medications have been used to treat Type 2 diabetes. More recently, GLP-1

[17] *Warning Letters*, Compliance Actions and Activities, FDA, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters (last visited Mar. 22, 2025).

[18] Under 21 CFR § 20.64(d)(3), "The consideration of regulatory enforcement action based upon a particular record shall be deemed to be closed with the meaning of this action . . . [i]f it relates to administrative action, ***when a final decision has been made not to take such action*** or such action has been taken and the matter has been concluded." 21 CFR § 20.64(d)(3) (emphasis added).

[19] 21 CFR § 20.64(d)(3).

medications have skyrocketed in popularity, gaining traction as "weight loss agents."[20] According to published studies, while "[t]he amount of new patients prescribed GLP-1s for diabetes decreased by almost 10% between 2011 and 2023 … those who were prescribed the drugs for obesity or other obesity-related conditions more than doubled during the same time period, particularly since 2020."[21]

56. Starting in spring 2022 through December 2024, four GLP-1 medications, including those indicated for weight loss (as opposed to indicated only for use to treat Type 2 diabetes) were added to the FDA's drug shortage list due to a major increase in patient demand.

57. On March 31, 2022, the FDA placed semaglutide injections, known by their brand names, Ozempic® and Wegovy®, on the shortage list.

58. On or around December 15, 2022, the FDA placed tirzepatide—by brand names, Mounjaro® and Zepbound®—on the drug shortage list due to increased demand for the drug.

59. Ozempic®, Wegovy®, Mounjaro®, and Zepbound® are all manufactured and distributed by major pharmaceutical companies.

60. The addition of semaglutide and tirzepatide to the FDA drug shortage list created an opening for compounding pharmacies and outsourcing facilities to compound semaglutide and tirzepatide to help ease the effects of the drug shortages.

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[20] Grace Niewijk, *Research shows GLP-1 receptor agonist drugs are effective but come with complex concerns*, Univ. of Chicago Medicine, (May 30, 2024). https://www.uchicagomedicine.org/forefront/research-and-discoveries-articles/research-on-glp-1-drugs.

[21] Arianna Johnson, *GLP-1s Are Growing In Popularity For Weight Loss But Losing Steam Among People with Diabetes, Study Suggests*, Forbes, (July 23, 2024) https://www.forbes.com/sites/ariannajohnson/2024/07/22/glp-1s-are-growing-in-popularity-as-weight-loss-drugs-but-losing-steam-among-diabetics-study-suggests/ (citing a study published in the Annals of Internal Medicine).

61. On December 19, 2024, the FDA issued a decision declaring that shortages of tirzepatide injection products (Mounjaro® and Zepbound®) had been resolved.[22] To prevent disruptions in distribution, the FDA announced it would not immediately take enforcement actions in connection with litigation on compounding pharmacies and outsourcing facilities currently compounding essentially copies of tirzepatide injections. The FDA announced that, for state-licensed pharmacies under section 503A that are compounding, distributing, or dispensing tirzepatide injections, it would begin enforcement on February 18, 2025, 60 days from the date of the announcement declaring an end to the shortage. For outsourcing facilities operating under section 503B that are compounding, distributing, or dispensing tirzepatide, the FDA would begin enforcement on March 19, 2025, 90 days from the date of the announcement declaring an end to the shortage.

62. The FDA's decision to remove tirzepatide from the drug shortage list was immediately challenged by Outsourcing Facilities Association and North American Custom Laboratories, L.L.C. (d/b/a Farmekeio Custom Compounding).[23] On or around October 11, 2024, the FDA announced that it would not take enforcement action against the plaintiffs and their members while it reevaluated the decision to remove tirzepatide from the drug shortage list.

63. The manufacturer of semaglutide injections known by their brand names, Ozempic® and Wegovy®, pushed back on the FDA's addition of semaglutide to the FDA Shortages List and 503B Bulk Drug Substances List. On or around October 21, 2024, the manufacturer, through its counsel, submitted a Citizen Petition pursuant to 21 C.F.R. § 10.30 to

[22] U.S. Food & Drug Administration, Declaratory Order: Resolution of Shortages of Tirzepatide Injection Products (Mounjaro® and Zepbound®) (Dec. 19, 2024).
[23] Complaint, *Outsourcing Facilities Assoc. v. FDA*, No. 4:24-cv-953 (N.D. Tex. Oct. 7, 2024), ECF No. 1.

the FDA to oppose the Outsourcing Facilities Association's nomination of semaglutide to the 503B Bulk Drug Substances List. In sum, the Petition argued that the addition of semaglutide to the 503B Bulk Drug Substances list would be improper because nothing about the FDA-approved semaglutide medications "ma[d]e them medically unsuitable to treat certain patients," arguing that there is no "clinical need to compound semaglutide medications."[24]

64. At the same time, on or around October 22, 2024, the manufacturer, through its counsel, also nominated semaglutide products to the list of drug products that "present demonstrable difficulties for compounding pursuant to the [FD&C Act]" sections 503A(b)(3) and 503B(a)(6). As previously noted, while the final proposed rule has not been made public, if semaglutide products were to be added to the FDA's DDC List once the proposed rule is finalized, semaglutide products would not qualify for statutory exemptions, and therefore could not be legally compounded under sections 503A or 503B, respectively.

65. The FDA announced on February 21, 2025, that there was no longer a shortage of Ozempic® and Wegovy®. As it did when tirzepatide was taken off the shortage list, the FDA stated that compounding pharmacies would be given a grace period of 60 to 90 days. The Outsourcing Facilities Association filed a lawsuit against the FDA on February 24, 2025, for declaring that the shortage of Ozempic® and Wegovy® was over.

BACKGROUND ON EMPOWER

66. Founded in 2008 by Shaun Noorian, Empower provides compounding and outsourcing services that specialize in creating patient-specific medications tailored to individual

[24] Per FDA rules governing compounding, a drug may be compounded for a patient who cannot be treated with an FDA-approved medication, such as a patient who has an allergy to a certain dye and needs a medication to be made without it, or an elderly patient or a child who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form. In this situation, the FDA considers there to be a "clinical need" to compound the drug at issue.

needs. From the outset, Empower has dedicated itself to providing access to quality, affordable products through the compounding process. Empower's mission is "[t]o produce innovative medications to help people live healthier, happier lives."

67. Empower operates a 503A pharmacy under the name "Empower Pharmacy." Separately, Empower operates a cGMP-compliant 503B outsourcing facility in Texas and is opening another in New Jersey under the name "Empower Pharma." Through both arms of Empower's business, Empower is able to create personalized products for specific patients and help ease drug shortages by fulfilling excess demand and providing access to specialized medications to patients, providers, hospitals, clinics, and pharmacies.

68. Empower's first FDA-registered 503B Outsourcing Facility opened in 2016. In 2021, Empower opened a new facility in Houston, Texas. In 2024, Empower expanded its 503B outsourcing capabilities by acquiring a new outsourcing facility in New Jersey. In compliance with FDA regulations, Empower's 503B outsourcing facilities all meet cGMP standards.

69. Empower Pharmacy is Pharmacy Compounding Accreditation Board ("PCAB") certified, having obtained its PCAB accreditation in 2017. PCAB accreditation is a system of quality and safety standards created by leading experts in the compounding pharmacy industry. The accreditation process is rigorous and includes steps such as extensive on-site inspections and a close review by experts of an applicant's compounding policies and procedures.

70. Within its first few years in operation, Empower Pharmacy achieved licensure in all 50 states, enabling it to ship compounded products to patients nationwide.

71. Empower Pharmacy is also authorized to dispense, administer, distribute, and compound controlled substances by the United States Drug Enforcement Agency ("DEA"). Empower Pharmacy is in good standing with the DEA and, like all areas of Empower's business,

has robust operating procedures in place to prevent and minimize the diversion of controlled substances.

72. Since Empower's founding, it has continued to grow, increasing the number of patients it is able to serve, and thereby improving patients' access to affordable medications tailored to their specific needs. Throughout the growth process, Empower has maintained a demonstrated commitment to ensuring the safety and quality of the products it compounds. For example, Empower has continually maintained its PCAB Accreditation. Moreover, Empower has invested substantial resources into its safety and compliance program.

73. A core part of Empower's business model is its commitment to applying innovative technology solutions to help grow its business and serve more patients. Empower's integration of technology into its operations has set it apart from other compounding pharmacies, increasing its ability to efficiently compound products safely. As of 2023, Empower Pharmacy—its 503A pharmacy—was filling approximately 15,000 custom-compounded prescriptions a day, helping millions of patients access medications to improve their quality of life. Empower's ability to safely and dependably compound and dispense this volume of compounded products is one of the primary characteristics that differentiates it from other compounding pharmacies. Empower Pharmacy is the only compounding pharmacy capable of compounding and dispensing this volume.

74. Empower is capable of compounding a wide variety of products spanning across a multitude of treatment areas which include men's and women's health, weight management, longevity, dermatology, hormone replacement, IV nutrition, sexual health, and mental health. Empower only compounds and ships products that are permitted to be compounded under federal and state laws and regulations.

LEGITSCRIPT'S UNREASONABLE RESTRAINTS OF TRADE, COMMERCIAL DISPARAGEMENT, AND TORTIOUS INTERFERENCE

I. LegitScript Unreasonably Restrained Trade by Orchestrating a Group Boycott, Tying Certification to the Purchase of Products from LegitScript-Certified Competitors, and Tortiously Interfering with Empower's Existing and Prospective Business Relations.

75. Empower's business depends on its ability to sell and distribute its products to customers who interact directly with patients seeking compounded products. These distribution channels necessarily include telemedicine providers and online pharmacies that contract with Empower for the supply of compounded products and that need a LegitScript Certification to advertise on leading internet and social media platforms.[25]

76. LegitScript has engaged in the biased and discriminatory enforcement of rules it imposes on applicants seeking certification in a manner that has directly impacted Empower and unreasonably restrained competition. Due to LegitScript's power in the market for certification of telemedicine providers and online pharmacies and its self-appointed function as a gatekeeper for such entities seeking to advertise with the leading search engine and social media platforms, LegitScript is in a position to impose terms and conditions on applicants for certification that they cannot afford to refuse and that would not be accepted in a competitive market. LegitScript's monopoly power has allowed it to go beyond the mere announcement of its terms and conditions and to enforce them in a biased and discriminatory manner against Empower, thereby depriving Empower of free and fair access to distribution channels and customers needed

[25] Generally, telemedicine can be defined as the use of telecommunications technologies to support the delivery of medical, diagnostic, and treatment-related services usually by doctors. U.S. FCC, *Telehealth, Telemedicine, and Telecare: What's What*, https://www.fcc.gov/general/telehealth-telemedicine-and-telecare-whats-what (last visited Mar. 22, 2025). Generally, the term "online pharmacy … means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet." 21 U.S.C. § 802(52)(A).

to compete on the merits against entities that are LegitScript-certified. This is not a new tactic employed by an organization seeking to set standards for an industry, but rather one that has been repeatedly rejected by the Supreme Court in instances such as this in which a private entity seeks to impose rules that advantage members of an association or entities that have been approved by an organization to the competitive disadvantage of those that have not.

A. LegitScript Has Enforced Its "Affiliates" Rule in a Biased Manner to Unlawfully Coerce Customers to Stop Doing Business with Empower to the Competitive Advantage of Entities It Has Already Certified.

77. In connection with its Healthcare Merchant Certification, LegitScript has adopted and enforced an "Affiliates" rule to prohibit entities that are LegitScript-certified or seeking certification from doing business with Empower and other entities that are not LegitScript-certified, to the competitive advantage of entities that are already certified.

i. LegitScript Has Adopted Increasingly Anticompetitive Rules Prohibiting Applicants and LegitScript-Certified Entities from Doing Business with Entities that Are Not LegitScript-Certified.

78. LegitScript's Healthcare Merchant Certification Terms and Conditions provided in connection with its Healthcare Merchant Certification Standards previously included a provision stating that "any person or entity that exercises control over, or participates in, the business must not be affiliated with or control any other entity that violates these standards." Ex. 1 at 2; Ex. 2 at 3.

79. Sometime thereafter in or around May 2022, LegitScript updated its Healthcare Merchant Certification Standards to expand its interpretation of its "Affiliates" rule. In addition to the more typical understanding of "Affiliates," referring to entities that exercise control over or directly participate in the business, the term "Affiliates" was expanded to further include "any individual, business, or entity who previously, currently, or is expected to have a commercial

and/or professional relationship with the applicant organization or its principals." For example, this includes, but is not limited to, supplying "wholesalers, co-owned companies, and ***partner pharmacies.***" Ex. 3 at 2 (emphasis added).

80. Empower and suppliers, however, generally are not "affiliates" of their customers in the legal sense such that it is suspiciously strained to apply such a designation in this context. The term "affiliate" instead is commonly understood to refer to a corporation that is related to another corporation by shareholdings or that is effectively controlled by another entity as a result of common ownership, more in line with LegitScript's original definition of the term. However, to be clear, none of the customers that LegitScript has prohibited from doing business with Empower are controlled by common ownership governing Empower.

81. In any event, prior to 2022, LegitScript's "Affiliates" rule notably excluded "partner pharmacies" from its definition. Over time, however, LegitScript required applicants not only to provide more information relating to the pharmacies with which they did business on the basis that they were purported "affiliates," but further began requiring that pharmacy suppliers either already be LegitScript-certified or become LegitScript-certified.

82. By no later than January 2025, LegitScript's Healthcare Certification Questionnaire, which provides "the questions that merchants are required to answer when applying for LegitScript Healthcare Certification," stated as follows:

> Does your business utilize a partner pharmacy? A partner pharmacy is defined as a pharmacy utilized by an applying entity to fulfill and dispense prescription medication orders to patients of the applying entity. ***Please note, partner pharmacies are required to be certified through LegitScript.***

Ex. 4 at 4 (emphasis added).

83. In short, LegitScript defined pharmacy suppliers as "affiliates" and then increasingly prohibited customer applicants and LegitScript-certified entities from doing business with purported "affiliates" or pharmacies that were not LegitScript-certified for some basis other than competition on the merits.

84. LegitScript's Application Certification Checklist further asked applicants if they had "searched and verified your partner pharmacy's LegitScript Certification status" to determine if their partner pharmacy is "'Certified' or 'Legitimate': If yes, great. Please be ready to have the pharmacy representative email us to confirm this affiliation. If not, please confirm they are ready and willing to apply for their own certification." Ex. 5 at 2.

85. Notably, as discussed below, Empower was not only "ready and willing" to apply for its own certification, but repeatedly sought certification only to be denied certification based on pretextual and discriminatory interpretations of LegitScript's standards.

86. As of January 2025, LegitScript's Healthcare Questionnaire further instructed, "***Please note, all partner pharmacies are required to be certified through LegitScript***." Ex. 4 at 4 (emphasis added).

87. Most recently, however, LegitScript has further updated its Healthcare Merchant Certification Standards to provide that:

> A merchant's partners, defined as organizations essential to supporting the applicant's continuum of care, ***such as partner pharmacies responsible for the fulfillment of prescription medication to patients, are generally required to be LegitScript-certified or accredited by another recognized body, with limited exceptions permitted only at LegitScript's sole discretion.***

Ex. 6 at 2 (emphasis added).

88. LegitScript's changes over time to this "Affiliates" rule as it pertains to partner pharmacies suggest that it has agreed to make exceptions to this rule to the benefit of some, but

not all, LegitScript-certified entities or their suppliers to the competitive disadvantage of Empower and other suppliers to entities that have not benefited from LegitScript's agreement to arbitrarily lessen restrictions on only certain LegitScript-certified entities and their pharmacy partners. The fact that LegitScript has not always required that its applicants and certified entities purchase solely from LegitScript-certified entities—both before LegitScript implemented the rule and now with respect to exceptions LegitScript arbitrarily makes to the rule—demonstrates that the rule is not reasonably necessary to achieve any procompetitive benefit and thus unreasonably and unjustifiably restrains competition.

89. Moreover, if this revised rule were fairly applied to Empower, Empower would likewise benefit from this exception as a result of "being accredited by another recognized body," namely PCAB.

90. But to the contrary, as described below, LegitScript has instead continued to prohibit LegitScript-certified entities and applicants from doing business with Empower, thereby restraining Empower's ability to compete on a level playing field against any pharmacy partners that LegitScript agrees to provide a competitive advantage by permitting them to supply LegitScript-certified entities and applicants under its admittedly "limited exception" to its otherwise prohibitive "Affiliates" rule.

91. LegitScript's rules further require that applicants "fully disclose affiliates in the application" as well as any business the applicant "is expected to have a commercial and/or professional relationship with" and that the "failure to disclose all Affiliates may result in denial or revocation of the application." Ex. 7 at 1.

92. As discussed below, Empower's customers have correspondingly communicated that they had informed LegitScript that Empower had a supply agreement with them and that

they expected to continue using Empower as its pharmacy supplier prior to being informed by LegitScript that they were prohibited from working with Empower. Accordingly, LegitScript interfered with these business contracts and relationships with full knowledge of Empower's contracts and business expectations. Indeed, LegitScript implemented rules requiring such disclosures with that apparent purpose and resultant effect.

ii. LegitScript Has Increasingly Enforced Rules Prohibiting Applicants and LegitScript-Certified Entities from Doing Business with Empower to the Benefit of LegitScript-Certified Competitors.

93. In the last several years, LegitScript has increasingly and repeatedly pointed to its "Affiliates" rule in communications with Empower's customers as a basis for prohibiting them from doing business with Empower if they wanted to become certified.

94. In early 2021, LegitScript did not prohibit applicants from working with Empower to the same severe degree that it has over time, even though a version of LegitScript's "Affiliates" rule was already in effect. Ex. 2 at 3.

95. For example, on or around January 11, 2021, one of Empower's customers, a telemedicine provider, was in the process of applying for a LegitScript Certification and contacted Empower. As a part of LegitScript's certification process, the customer was asked to identify its pharmaceutical suppliers. Over email, Empower's customer communicated that:

[redacted]

[redacted] On or around January 21, 2021, a customer representative further clarified: [redacted]

96. While ratcheting up the restriction, in early February 2022, at least one customer still did not understand LegitScript's position as one fully prohibiting the customer from working with Empower. On or around February 22, 2022, a LegitScript representative told a telehealth service provider customer applying for LegitScript Certification, that "[a]n affiliation with Empower Pharmacy (empowerpharmacy.com) ***could*** … constitute a barrier to certification, in line with LegitScript Certification Standard #6 on Affiliates." *See* Ex. 8 at 3 (emphasis added).[26]

97. By November 2023, however, LegitScript's enforcement of its "Affiliates" rule had escalated. LegitScript began enforcing the rule against Empower, even though by its own admissions, the rule did not necessarily apply to Empower, which it conceded at the time was not "partnered" with the customer. On or around November 2, 2023, a LegitScript representative stated to one of Empower's customers at the time that:

> We understand [Empower's customer] is ***not*** partnered with Empower Pharmacy. However, LegitScript Certification Standard 7: Affiliates, states "a merchant's Affiliates must comply with all program standards. This means any person or entity that exercises control over or participates in the business, including but not limited to, pharmacy, business or medical practice, website, staff, any associated medical personnel, must not be affiliated with or control any other entity that violates these standards."

The LegitScript representative concluded by informing Empower's customer in no uncertain terms that "[a]ffiliation with Empower Pharmacy ***would therefore constitute a barrier to certification …. [The customer] will need to find a new pharmacy in order to move forward in the review process***." LegitScript's biased and discriminatory application of the "Affiliates" rule against Empower despite acknowledging it should not apply on the face of the rule supports the conclusion that LegitScript has been stretching and broadening its rules to block competition from Empower.

[26] As of November 2024, LegitScript's "Affiliates" rule was Certification Standard 7 (Ex. 3 at 2) and was later changed to Certification Standard 5 (Ex. 6 at 2).

98. As it turned out, LegitScript's escalated enforcement of its "Affiliates" rule against Empower in November 2023 was no fluke. In an email dated December 27, 2023, from the LegitScript Certification Team to another Empower telemedicine customer, LegitScript stated: "Affiliation with Empower Pharmacy ***would*** … ***constitute a barrier to certification*** … under LegitScript Healthcare Merchant Certification Standard 7: Affiliates" (emphasis added).

99. Thereafter, LegitScript continued to aggressively enforce its "Affiliates" rule into 2024 and began singling out a business relationship with Empower as a barrier to certification. For example, on or around January 22, 2024, another Empower customer was informed by a member of LegitScript's certification team that "***we [LegitScript] do not allowed [sic] any of our certified clients to work with Empower Pharmacy***." Earlier in the same email chain, the LegitScript representative also informed Empower's customer that: "***We do not frequently deny applications unless applicants are unwilling to come into compliance***," implying that Empower's failure to become LegitScript certified was due to an unwillingness to comply with LegitScript standards. In response to LegitScript's email, Empower's customer informed LegitScript that it [redacted] Ex. 9 at 1.

100. LegitScript's admission that it has the power not to "allow" or to prohibit all of its applicants and "certified clients" from working with Empower reflects LegitScript's market power, as does the applicants' agreement to be bound by LegitScript's anticompetitive and exclusionary rule directed at Empower.

101. LegitScript's communications singling out Empower to its customers continued thereafter. On or around August 5, 2024, another Empower customer informed Empower: [redacted]

[redacted]

The representative consequently asked to confirm that Empower had closed its account.

102. While LegitScript previously informed Empower's customers that an affiliation with Empower "could" constitute a barrier to certification, by no later than November 2, 2023, and continuing thereafter, LegitScript has exercised its market power by requiring Empower's customers to stop doing business with Empower in contrast to what those customers would otherwise do in a competitive market absent LegitScript's coercion.

103. From there, LegitScript outlined only one path forward for Empower's customers if they wanted to move forward with their LegitScript Certification and, ultimately, to become LegitScript certified: comply with LegitScript's "Affiliates" rule and "find a new pharmacy in order to move forward in the review process."

104. Language from LegitScript's Healthcare Certification Questionnaire uploaded in January 2025 made it equally clear that applicants for certification could only partner with LegitScript-certified pharmacies. LegitScript's Questionnaire asked applicants: "Does your business utilize a partner pharmacy?" The Questionnaire then went on to state: "A partner pharmacy is defined as a pharmacy utilized by an applying entity to fulfill and dispense prescription medication orders to patients of the applying entity. ***Please note, partner pharmacies are required to be certified through LegitScript.***" Ex. 4 at 4 (emphasis added).

105. Accordingly, LegitScript used to tell Empower's customers that LegitScript could certify them irrespective of whether Empower was certified by LegitScript or not, so long as Empower "ships out medication[s] [that] are licensed," but then began affirmatively requiring that the customers stop doing business with Empower in order to become LegitScript-certified.

106. The fact that LegitScript did not previously require pharmacy suppliers like Empower to be LegitScript-certified—*and only that pharmacy suppliers had to be "licensed"*—demonstrates that LegitScript's increasingly anticompetitive interpretation and enforcement of the "Affiliates" rule is not reasonably necessary to achieve any legitimate, procompetitive justification. To the contrary, LegitScript's increasingly anticompetitive enforcement of its rules is instead reflective of its growing market power over applicants and certified entities and its power to exclude competitors to the competitive advantage of LegitScript-certified entities and one or more of their suppliers with which LegitScript has close ties.

iii. Empower's Customers Have Capitulated to LegitScript's Coercive Demands to Agree to Be Bound By LegitScript's Unlawful Enforcement of Its "Affiliates" Rule.

107. Faced with the choice to either abandon their applications for LegitScript Certification and, consequently, lose the ability to place ads on major search engine and social media platforms, many of Empower's customers capitulated to LegitScript's anticompetitive demands. For example, as noted above, one customer informed LegitScript that it "certainly will find an alternative vendor" and another closed its account with Empower.

108. As a result of LegitScript's enforcement of its "Affiliates" rule against Empower, numerous customers with which Empower had existing supply relationships stopped doing business with Empower. These customers include, but are not limited to, [redacted] Representatives of these customers expressly informed Empower's sales team that their decisions were due to concerns related to LegitScript and the information communicated by LegitScript to these customers.

109. A significant number of customers additionally decreased the amount of business they were expected to conduct with Empower because of LegitScript's enforcement of its "Affiliates" rule against Empower. Empower's sales team was informed by customers including, but not limited to [redacted] that the reason for the decrease in the volume of business was due to concerns related to LegitScript and the information communicated by LegitScript to these customers.

110. In some instances, prior to LegitScript's communications, customers had been increasing the volume of purchases from Empower. For example, in fiscal year 2022-2023, [redacted] was steadily increasing its volume of business conducted with Empower. However, due to concerns with LegitScript, in 2024, the growth stopped, and [redacted] instead began reducing its volume of purchases from Empower due to concerns related to LegitScript.

111. LegitScript's enforcement of its "Affiliates" rule also resulted in prospective customers declining to engage with Empower due to LegitScript concerns. At least a dozen prospective customers, including, but not limited to, providers such as [redacted] informed Empower's sales team that a business relationship with Empower was not possible due to the prospective customers' concerns related to LegitScript.

112. Many of these customers—both existing and prospective—informed Empower's sales team that they were interested in working with Empower or continuing to work with Empower but could not sacrifice their ability to advertise on major search engine and social media platforms. Accordingly, in contrast to what would have happened in a competitive market in which Empower was free to compete for customers on the merits of its products, prices, and

services, LegitScript coerced Empower's customers to stop or refrain from doing business with Empower.

iv. LegitScript Has Disparaged Empower in Communications to Customers Resulting in Additional Reputational Harm.

113. LegitScript's aggressive enforcement of its "Affiliates" rule against Empower has also resulted in reputational harm to Empower. As LegitScript ramped up its enforcement of its "Affiliates" rule, it began communicating misleading information about Empower's regulatory history to Empower's customers. For example, in the November 28, 2023 correspondence between LegitScript and Empower's former customer [redacted], LegitScript wrote, without providing any meaningful context, that "Empower Pharmacy and its affiliates have facilitated the sale of drug products that visibly do not meet current regulatory requirements for medicines, including FDA regulatory allowances for compounded drug products." But Empower did not facilitate the sale of drug products in violation of FDA rules and regulations. As Empower noted in its response to the FDA, a number of the issues flagged by the FDA, including the FDA's contention that Empower and its affiliates had facilitated the sale of drug products that did not meet regulatory requirements, were the result of the FDA inspector conflating Empower Pharmacy's (503A pharmacy) conduct with that of Empower Pharma (503B outsourcing facility). Only the latter was being inspected, and, notably, federal regulations allow for a 503A pharmacy to compound drugs that a 503B outsourcing facility may not be able to compound. Nonetheless, Empower took corrective actions (e.g., with regards to drug labeling) to better distinguish between its 503A and 503B operations. None of this context was included in LegitScript's misleading and reckless communication.

114. In the same email communication, LegitScript also identified a prior regulatory issue brought by the California Board of Pharmacy against Empower. LegitScript informed the

customer that Empower Pharmacy was the subject of an "unresolved Accusation" filed in May 2022 by the California Board of Pharmacy. However, this statement was also misleading. LegitScript failed to mention that Empower had entered into a Stipulated Settlement Agreement with the California State Board of Pharmacy in January 2023 to resolve the regulatory matter in question. Critically, in entering the Stipulated Settlement Agreement, Empower made no admissions of wrongdoing. Once again, LegitScript's communication was stripped of any meaningful context, creating the impression that Empower had not resolved a regulatory matter.

115. LegitScript has also implied to Empower's customers that Empower is "unwilling" to come into compliance with LegitScript's standards. As described in more detail above, LegitScript told at least one of Empower's customers that "We do not frequently deny applications ***unless applicants are unwilling to come into compliance***," implying that Empower's failure to become LegitScript certified was due to an unwillingness to comply with LegitScript standards. Ex. 9 at 2 (emphasis added). To the contrary, Empower has repeatedly sought information from LegitScript to better understand what its standards are and what it requires for certification. LegitScript, however, has refused to respond substantively to Empower's questions. *See generally* Exs. 10, 11.

116. LegitScript's misleading communications to Empower's customers serve as further evidence of biased and discriminatory enforcement of its "Affiliates" rule against Empower and an anticompetitive intent to unfairly restrain competition from Empower. LegitScript's "Affiliates" rule does not give it carte blanche authority to commercially disparage Empower by communicating out-of-context and misleading information targeting Empower.

117. LegitScript's actions as a whole with regard to its "Affiliates" rule has resulted in Empower losing customers as well as sales from customers that remain, losing customer

goodwill, experiencing reputational harm diminishing its ability to win new business, and has restrained Empower's ability to access customers and distribution channels needed to compete on an even playing field.

v. LegitScript's Biased and Discriminatory Enforcement of Its "Affiliates" Rule Supports the Conclusion That Empower Has Been Targeted for an Anticompetitive Purpose and Effect.

118. The anticompetitive purpose and intent of LegitScript's expanded and escalated enforcement of its "Affiliates" rule against Empower, thereby cutting Empower off from distribution channels it needs to compete on an even playing field, is further supported by LegitScript's uneven enforcement of its "Affiliates" rule.

119. For example, Roman Health Ventures, Inc. (d/b/a Ro), a telemedicine provider, is a competitor of Empower's in the pharmaceutical market and a member of ASOP Global, as is Ro's supplier of GLP-1s with which LegitScript also has close ties. *See* Ex. 15 at 1.

120. On or around December 11, 2024, Ro announced a partnership to distribute tirzepatide from the large pharmaceutical manufacturer member of ASOP. Through the partnership, Ro would make tirzepatide "available as a treatment option with an on-label prescription from a ***Ro-affiliated provider***" via the large ASOP pharmaceutical manufacturer member. Based on how LegitScript had been enforcing its "Affiliates" rule against Empower—i.e., making a distribution partnership with Empower a barrier to becoming LegitScript certified—it was reasonable to expect that LegitScript would require both Ro and its now-partner pharmaceutical manufacturer to be LegitScript-certified. But this does not appear to be the case. While Ro is LegitScript-certified, its "Ro-affiliated provider" is not listed as a LegitScript-certified entity.

121. Under LegitScript's "Affiliates" rule as it has been communicated to Empower's customers, Ro would lose its LegitScript Certification by partnering with the non-LegitScript certified pharmaceutical supplier.

122. The apparent disparity between LegitScript's treatment of Empower compared to Ro is particularly concerning in the context of the reporting discussed above that LegitScript "carries out most of the operational level arrangements that are agreed at a level of principle" with ASOP members, including "private deals" to "block" pharmacies from the market.

123. As the reporter noted, "The unsurprising result is that the measures put in place by this closed and captured process are too broad, favoring the private interests of big pharma, limiting access to information and access to safe and affordable medicine."

124. As set forth above, LegitScript has entered into agreements unreasonably restraining trade among horizontal competitor resellers of compounded products by requiring that they agree to adhere to LegitScript's anticompetitive "Affiliates" rule to boycott Empower.

125. LegitScript's biased and disparate treatment of Empower, expanded interpretation and enforcement over time of the "Affiliates" rule, misleading and disparaging statements targeting Empower, preferential treatment of ASOP members and LegitScript-certified entities, and reporting that LegitScript carries out agreements reached with ASOP members through its business provide evidence that LegitScript has not only entered into unreasonable restraints of trade by organizing a downstream group boycott against Empower but has further done so as a result of an unlawful agreement with one or more Empower competitors.

vi. LegitScript's Expansion of Its "Affiliates" Rule Prohibiting LegitScript-Certified Businesses From Buying Products From Non-LegitScript Certified 503A Pharmacies or 503B Outsourcing Facilities Contravenes Draft FDA Guidance and Is Anticompetitive.

126. In line with LegitScript's ongoing use of its "Affiliates" rule to block certain pharmaceutical suppliers including Empower from customers and distribution channels needed to compete, on or around October 22, 2024, Empower learned of another variation of the "Affiliates" rule that LegitScript adopted that prohibits LegitScript-certified businesses from buying products from non-LegitScript certified 503A pharmacies or 503B outsourcing facilities.

127. LegitScript's articulation of this prohibition constituted yet another anticompetitive version of the "Affiliates" rule, now directed more specifically at compounding pharmacies and outsourcing facilities.

128. The anticompetitive purpose and effect of LegitScript's compounding and outsourcing version of its "Affiliates" rule is to clarify that LegitScript-certified 503A pharmacies are prohibited from doing business with 503B outsourcing facilities unless they are LegitScript-certified. Notably, this rule directly contravenes the Draft Guidance on Wholesaling issued by the FDA in June 2023.

129. As set forth above, the FDA's draft guidance, issued on or around June 27, 2023, clarified whether partnerships between state-licensed 503A pharmacies and 503B outsourcing facilities are permissible under the FD&C Act. Pursuant to the FDA's Draft Guidance on Wholesaling, state-licensed 503A pharmacies may purchase compounded medications from 503B outsourcing facilities for dispensing to patients with valid prescriptions. In other words, a 503B outsourcing facilities' direct sale or transfer of a drug it compounded to a state-licensed 503A pharmacy does not constitute "wholesaling" under the FD&C Act.

130. For example, pursuant to the FDA's Draft Guidance on Wholesaling, Empower Pharma, its 503B outsourcing facilities, is permitted to partner with, and directly sell or transfer compounded products to, 503A state-licensed pharmacies or federal facilities. Therefore, in a competitive, unrestricted market, 503A pharmacies serve as an additional distribution channel for 503B outsourcing facilities.

131. For 503A pharmacies, partnering with 503B outsourcing facilities may be beneficial for a number of reasons, including, but not limited to, potential mitigation of risks, reductions in operational costs, increased ability to provide expanded services to patients, and improvement in customer satisfaction.[27]

132. While 503A pharmacies tend to be smaller in size with overall less operational volume due to the nature of their business focused on compounding and dispensing products for individual patients based on existing prescriptions, 503B outsourcing facilities, especially Empower Pharma, tend to do business on a larger scale, have more resources at their disposal, and can benefit 503A pharmacies by providing streamlined products and services, such as by providing compounded products with consistent and professional labeling that increases patients' confidence in the consistency of the compounded products they purchase.

133. However, after the FDA published its Draft Guidance on Wholesaling in June 2023, LegitScript, once again, arbitrarily inserted itself into the distribution chain. Notwithstanding the fact that a 503B outsourcing facility's partnership with a 503A pharmacy falls outside the legal definition of an "affiliate" or "affiliation," LegitScript has taken it upon itself to construct

[27] Bruno Onwukwe & Celeste Zizzamia, *Partnerships Between 503A Pharmacies And 503B Outsourcing Facilities*, Pro. Compounding Ctrs. of Am. (Nov. 27, 2024), https://www.pccarx.com/Blog/partnerships-between-503a-pharmacies-and-503b-outsourcing-facilities.

yet another barrier between legitimate 503B outsourcing facilities, including Empower Pharma, and available distribution channels.

134. While, pursuant to the FDA's Draft Guidance on Wholesaling, 503B outsourcing facilities are free to partner with 503A pharmacies and vice versa, LegitScript clarified that it prohibited 503A pharmacies from seeking to partner with 503B outsourcing facilities that are not LegitScript-certified for their supply of compounded products. This is yet another way that LegitScript is restraining output of compounded products.

135. As with LegitScript's other restrictions, due to its power in the market for certification of telemedicine providers and online pharmacies and its ability to essentially deny these customers access to digital marketing channels, LegitScript has the power to coerce 503A pharmacies to comply with its mandate, choosing only from a restricted pool of 503B outsourcing facilities that LegitScript has deemed worthy, i.e., "legitimate," despite lacking the authority to make such a determination or the practical ability to ensure that such determination rests on a non-biased and non-discriminatory foundation.

136. Additionally, LegitScript's escalated enforcement of its "Affiliates" rule, which, began no later than the beginning of November 2023, coincided with the period following the FDA's publication of its Draft Guidance on Wholesaling just earlier that year.

137. LegitScript's inappropriate application of its "Affiliates" rule prohibiting LegitScript-certified businesses from buying products from non-LegitScript certified 503A pharmacies or 503B outsourcing facilities has the effect of requiring 503B outsourcing facilities to apply for LegitScript Certification when they did not previously need to because they are outsourcing facilities as opposed to pharmacies or telemedicine providers.

138. For example, during Empower's previous application cycles, Empower only sought certification for its 503A compounding pharmacy, *not* its 503B outsourcing facilities. Under this version of the "Affiliates" rule, in order to continue accessing its distribution channel to 503A pharmacies, Empower faces yet another restriction imposed by LegitScript and would need to secure LegitScript Certification for both its 503A compounding pharmacy and its 503B outsourcing facilities. As it is, Empower's 503B outsourcing facilities and 503A pharmacy fall outside the scope of telemedicine providers and online pharmacies, therefore falling outside the scope of LegitScript's purported mission: "making internet and payment ecosystems safer and more transparent."[28] However, LegitScript's imposition of its anticompetitive and restrictive rules on customers demanding they only do business with LegitScript-certified entities increases the need for compounding pharmacies and outsourcing facilities to obtain certification to avoid being boycotted.

139. The clarified breadth of LegitScript's "Affiliates" rule thus further restrains trade by cutting off both arms of Empower's business—its 503A compounding pharmacy and its 503B outsourcing facilities—from its customers.

B. LegitScript's "Affiliates" Rule Violates the Law in Multiple Ways.

140. LegitScript's coercion forcing customers to agree not to purchase compounded products from Empower or else be denied certification or have their certification revoked violates the law in multiple ways.

141. First, by coercing customers to cancel supply agreements and accounts with Empower, LegitScript has tortiously interfered with Empower's contracts and prospective business advantage.

[28] About Us, LegitScript, https://www.legitscript.com/about/ (last visited Mar. 22, 2025).

142. Second, LegitScript's coercion of customers to force them to boycott Empower was exclusionary and predatory conduct in that it impairs the opportunities of rivals to LegitScript-certified suppliers on some basis other than efficiency, does not further competition on the merits, and/or restrains competition in an unnecessarily restrictive way. Threatening to cut off access to certification is particularly coercive where, as here, the buyers cannot reasonably compete without the seller's product—namely, LegitScript's certification. Specifically, LegitScript orchestrated a group boycott and "concerted refusal to deal" among horizontal competitor resellers of compounded products by entering into agreements prohibiting them from purchasing Empower's products. LegitScript further enforced compliance with the group boycott by telling applicants that LegitScript would not only refuse to certify applicants if they did business with Empower but that it would also revoke certifications if they did so. Whether this group boycott is considered in isolation or in the broader context of LegitScript's biased and discriminatory conduct favoring LegitScript-certified entities and reported implementation of agreements entered with members of ASOP or otherwise, LegitScript's boycotting conduct to deny Empower relationships it needs to compete, such as with its customers, is unlawful under either the per se rule or under the rule of reason because it has had actual adverse effects on the market by restraining output during the national shortage of GLP-1s and by requiring patients to buy more expensive products instead from brand competitors and others. LegitScript has harmed the competitive process by prohibiting Empower's customers from purchasing the products they would have purchased from Empower in a competitive market based on the merits of Empower's quality, pricing, and services.

143. LegitScript's implementation and enforcement of the "Affiliates" rule is also anticompetitive because it is exclusionary towards entities that would otherwise compete directly

with LegitScript to provide higher quality certifications. By restricting applicants and LegitScript-certified entities from doing business with suppliers that are certified by other accreditation bodies that are not recognized by LegitScript, like the PCAB, LegitScript blocks other accreditation bodies from serving as reasonable substitutes for LegitScript's certification. LegitScript's "Affiliates" rule thereby renders formerly alternative certifications unsuitable in that they can no longer help accredited entities increase, or even maintain, sales to customers that have been cut off by LegitScript, depriving those certifications of any comparable value to their accreditation customers. LegitScript has thus distorted competition on the merits for certifications that would otherwise be based on the quality of the certification and review process, pricing, and services because entities are instead now coerced to seek certification from LegitScript either alone or in addition to other accreditation entities, which would be a waste of resources for entities seeking to continue selling to their customers that are LegitScript certified or seeking LegitScript certification. In short, LegitScript's anticompetitive use of the "Affiliates" rule helps LegitScript maintain and increase its market and monopoly power by protecting it from losing customers to more legitimate accreditation bodies regardless of how poorly LegitScript applies and monitors its sham standards.

144. Third, LegitScript's refusal to provide certification unless Empower's customers agree to purchase products from LegitScript-certified entities and/or agree not to purchase products from Empower constitutes unlawful tying under Sections 1 and 2 of the Sherman Act and state antitrust laws. LegitScript has expressly conditioned the ability to purchase the tying product, certification, on the buyer's agreement to purchase a different, tied product (products sold by LegitScript-certified entities) and/or not to purchase Empower's compounded products.

145. LegitScript's imposition of these unreasonably restrictive boycotting and tying agreements on Empower's customers has substantially foreclosed Empower's access to key customers and the most efficient distribution channels for its compounded products (i.e., through customers with which it had already established relationships and successful sales channels).

146. While the cancelling of accounts and orders demonstrates an actual anticompetitive effect on the market, per se condemnation of this conduct without inquiry into actual market conditions is also appropriate in this case because LegitScript exploited control over the tying product (certification) to force the buyer into the purchase of a tied product (products sold by LegitScript-certified entities) that the buyers might have preferred to, and indeed tried to, purchase elsewhere from Empower on different terms.

147. LegitScript's tying agreements affect a substantial amount of interstate commerce, with customers diverting hundreds of millions of dollars' worth of compounded products every month as a result of LegitScript's coercion, and LegitScript has actually tied the sale of two distinct products, namely certification and the compounded products sold separately.

148. As discussed in more detail above, by virtue of LegitScript's agreements restricting access to advertising on key search engine and social media platforms, LegitScript has appreciable market power in the tying market for certification, as demonstrated by LegitScript's ability to require purchasers to accept rules and suppliers that would not have been agreed to in a competitive market.

149. LegitScript has succeeded in raising Empower's costs and substantially foreclosing access to customers, critical relationships, and the distribution channels Empower and other compounding pharmacies need access to in order to meaningfully compete with LegitScript-certified suppliers and other competitors given an arbitrary pass from LegitScript's rules by

wielding LegitScript's economic power derived from its market and monopoly power in the certification market.

150. Finally, even if LegitScript's agreements with customers were each considered on an individual basis, rather than together as they should be considered to assess the cumulative impact of LegitScript's anticompetitive conduct, they still violate Section 1 of the Sherman Act and state antitrust laws as unreasonable restraints of trade that cannot be justified by any legitimate, procompetitive benefit achieved by cutting Empower off from its customers, restricting output, and depriving customers of their preferred supplier and terms as well as competition across alternative suppliers.

151. These agreements are unreasonably restrictive, entered or enforced with the exclusionary purpose and effect of restraining competition from Empower and with the further anticompetitive effect of maintaining and enhancing LegitScript's market and monopoly power by requiring entities that would not otherwise need LegitScript Certification to seek certification or be cut off from access to key customers and the most efficient and critical distribution channels.

152. In short, LegitScript has harmed the competitive process both by restraining competition on the merits for sales to LegitScript-certified entities at the better prices and quality that would otherwise prevail in a competitive market and also by abusing its market power by forcing entities to seek certification from LegitScript when they would have preferred to obtain certification, or have already obtained certification as in Empower's case, from another accreditation organization that is not a for-profit company seeking to unlawfully insert itself as a private gatekeeper distorting competition in markets that are already regulated.

153. LegitScript's requirement that Empower's customers cut ties with Empower in order to get certified cannot be justified by any legitimate, procompetitive purpose. The fact that LegitScript previously required only that pharmacy suppliers be "licensed" demonstrates that its new restrictions are not reasonably necessary to achieve any purported safety concern, for example, which has been rejected as a procompetitive justification in antitrust cases in any event as it is not based on efficiency considerations. As discussed further below, moreover, LegitScript-certified entities have had far more serious regulatory issues than Empower indicating that any justification based on purported safety issues would be pretextual at best. LegitScript, moreover, could achieve any such purported justification in a less restrictive way by engaging with Empower to permit it to demonstrate its compliance with any legitimate standards. But to the contrary, LegitScript instead imposed an arbitrary waiting period on Empower's ability to do so and has repeatedly declined to engage in discussions regarding LegitScript's standards and Empower's compliance with those standards. *See, e.g.*, Exs. 10, 11.

154. Thus, even if restrictive standards would be effective to some extent in protecting legitimate procompetitive goals, which here they are not, these provisions still violate the antitrust laws because they impair the opportunities of rivals in an unnecessarily restrictive way.

155. As discussed above, these anticompetitive tying and group boycott agreements with Empower's customers have been effective, with numerous customers either cancelling accounts and orders or substantially decreasing orders as the direct result of LegitScript's unlawful conduct. The customers' capitulation to LegitScript's coercion is particularly extraordinary given the national shortage over GLP-1s during this time period and the substantial price gap between the branded and compounded alternatives.

II. LegitScript's Arbitrary Denial of Empower's Healthcare Certification and Website Classification of Empower as an "Unapproved" Pharmacy Is Further Evidence of Its Biased and Discriminatory Practices That Unreasonably Restrain Trade.

156. LegitScript holds itself out as offering market participants "a recognized seal of approval that enables businesses to showcase their compliance, unlock opportunities to advertise, and accept digital payments," among other things.

157. Entities like LegitScript that take it upon themselves to sell their certification or "seal of approval" to industry participants based on guidelines, standards, or rules they set for industry participants in order to obtain certification or approval have long raised antitrust concerns given their power to provide a competitive advantage to some market participants with an economic interest in the standard set for certification to the competitive disadvantage of others.

158. To protect against the manipulation of certification standards by competitors, courts assess whether certification standards have been implemented or enforced in a manner that restrains competition and insulates approved entities from competition through the biased or arbitrary application of standards. Where, like here, there has been a biased and arbitrary application of certification standards, the conclusion can be drawn that rules that were purportedly implemented to help maintain high quality or safety standards for an industry instead have the real purpose and effect of unreasonably restraining free and fair competition on the merits of the competitors' products, services, and prices.

159. As set forth in detail below, LegitScript has repeatedly refused to certify Empower based on apparently pretextual bases while *granting* certification to other entities with far more serious regulatory issues, including to entities *that have pled guilty* to violations of law relating to their pharmacy practices. LegitScript meanwhile publicly touts the "safety" and "legality" of

pharmacies that have likewise admitted to serious charges or that are currently defending government enforcement actions based on serious violations of law and claims that the pharmacies' illegal conduct has even resulted in patients' deaths.

A. LegitScript Unreasonably and Arbitrarily Denied Certification to Empower Despite Empower's Demonstrated Efforts to Achieve Compliance.

160. In 2018, Empower Pharmacy, Empower's 503A compounding pharmacy, applied for a LegitScript Healthcare Merchant Certification given LegitScript's growing importance to Empower's customers.

161. After LegitScript denied Empower Pharmacy's first application, a second application was submitted in April 2021. LegitScript again denied the application, citing open regulatory matters and Affiliate-related issues as grounds for denial. In November 2022, Empower informed LegitScript that it had corrected several issues identified by LegitScript, and that since its April 2021 application, "Empower Pharmacy has added internal leadership and external oversight, including experts with decades of experience in pharmacy compliance, operations, and process improvement," and "has restructured its manufacturing, quality, and compliance departments to provide for greater oversight." Empower diligently updated LegitScript with its plans for ongoing compliance and corrective actions.

162. As noted above, LegitScript has admitted to Empower's customers that it does "not frequently deny applications unless applicants are unwilling to come into compliance." Ex. 9 at 2. As the founder of LegitScript, John Horton, wrote online, "[H]ey, want to get LegitScript certified? Not Hard. Operate legally."[29] Yet despite the extensive efforts Empower invested

[29] John Horton, *EFF's Emerging Alignment with Offshore Internet Pharmacies*, CircleID (Mar. 21, 2017), https://circleid.com/posts/20170321_eff_emerging_alignment_with_offshore_internet_pharmacies#11681 (including comment chain between John Horton, President of LegitScript, Gabriel Levitt, President of PharmacyChecker, and Jeremy Malcolm).

into addressing any issues raised by LegitScript, LegitScript again denied Empower's application. Empower appealed in January 2023.

163. In February 2023, Empower voluntarily updated its appeal application and provided Empower's quarterly updates to the FDA. Empower also informed LegitScript that "[t]o date, Empower is over 85% complete implementing change controls for the observations listed in its August 2022 Form 483"—again demonstrating that Empower was diligently taking corrective actions in response to the FDA's observations in a Form 483.

164. Yet, LegitScript denied Empower's application that same month, informing Empower that LegitScript was "unable to proceed" until it received copies of quarterly reports from Empower's settlement with the California Board of Pharmacy—a regulatory matter that Empower and the California Board had settled the year prior. In May 2023, Empower informed LegitScript that it was "in compliance at present with the terms of our [California Board of Pharmacy] probation"—which was operational in nature and did not impose disciplinary actions on Empower, but rather was aimed at ensuring ongoing compliance—and informed LegitScript that Empower continued to have proactive and positive engagement with the FDA.

165. Thereafter, after multiple rounds of Empower responding and complying with LegitScript's documentation requests, LegitScript denied the appeal in August 2023.

166. Empower submitted a new application in or around March 2024. This application, too, was rejected without a clear basis for denial. LegitScript acknowledged Empower's "dedication to improving compliance," yet required a number of ambiguous items to be "closed out" before Empower could move forward with certification, stating: "All state board of pharmacy consent orders, disciplinary action, and stipulation orders are required to be closed out. FDA acknowledgement that the response provided by Empower to the FDA Form 483 is

sufficient. We require inspection reports (both self-assessment and the assessment performed by the hired inspector) for Q2-Q4."

167. As discussed above, however, the FDA has no obligation to officially "close out" a Form 483 or a Warning Letter and can choose simply to not take any further action. Empower sought clarification as to what LegitScript was referring to with respect to "inspection reports … by the hired inspector" because it was unclear *which* hired inspector (i.e., the FDA's investigator or a state investigator) was being referenced. Upon follow up, LegitScript refused to provide any clarification.

168. Also, unlike previous denials, LegitScript imposed a wholly arbitrary six-month waiting period before Empower could submit a new application.

169. Empower was blindsided by LegitScript's imposition of a six-month waiting period—which LegitScript asserted was "essential to allow adequate time [for Empower] to demonstrate sustained compliance" with LegitScript's standards, suggesting that LegitScript acknowledged that Empower *had* already come into compliance with LegitScript's standards. *See* Ex. 12 at 1.

170. Given the lack of clarity from LegitScript's explanation of its reasons for denial, and to improve its approval chances in the future, Empower requested guidance from LegitScript as to its certification standards and the reasons underlying LegitScript's denials of Empower's prior applications. *See* Ex. 10. LegitScript refused to provide such information to Empower. LegitScript, however, thoroughly (and misleadingly) elaborated its purported reasons for denying Empower's applications to Empower's customers.

171. For example, LegitScript told one customer that "Empower Pharmacy was the subject of an October 2021 Warning Letter by the FDA which mentions that drug products

produced by Empower Pharmacy 'failed to meet the conditions of ***section 503B*** of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain provisions of the FDCA'" (emphasis added). However, this statement was false and misleading. As set forth above, Empower Pharmacy and Empower Pharma are subject to different regulations and standards, and LegitScript inappropriately conflated the two by stating that Empower Pharmacy was the subject of the Warning Letter referenced. LegitScript's error citing correspondence related to Empower's 503B facility as a basis for denying Empower Pharmacy's 503A LegitScript application further demonstrates that LegitScript lacks the resources necessary to administer a neutral certification process that reflects a full understanding of the complex regulatory frameworks governing the industry, rendering the process ripe for abuse by other industry participants, including Empower's competitors.

172. Lacking direct guidance, Empower pieced together an understanding of LegitScript's certification standards and process through LegitScript's website and communications to Empower's customers. LegitScript's own guidance states that it may grant a "probationary certification" to applicants that have been "subject to Disciplinary Action, pose a reputational risk to LegitScript, or have otherwise been deceptive, uncooperative, noncompliant, or not transparent, but have since sufficiently remediated to LegitScript's satisfaction and have satisfactorily demonstrated a commitment to compliance with LegitScript's standards." Ex. 7 at 4. LegitScript began offering probationary status in 2017. *See* Ex. 14 at 1. In a blog post on LegitScript's website attributed to LegitScript's former CEO and President, John Horton, he wrote that when applicants with problems in the past "indicate[] they have fixed the issue and intend to operate in compliance going forward," LegitScript is "hesitant not to approve them, as long as they remain licensed and are now fully legally compliant." *Id.* Per

LegitScript's own statements, "prior discipline alone doesn't mean that a pharmacy's only option is probationary – rather, it has to be pretty serious stuff." *Id.* at 2. Indeed, LegitScript affirmatively touts its ability to "help[] applicants identify and correct inadvertent errors in compliance with pharmacy and telemedicine regulations." Ex. 13 at 6.

173. As explained above, Empower has been transparent with LegitScript regarding any prior regulatory issues and has provided LegitScript with robust details on how it had or planned to remediate such issues. LegitScript itself has acknowledged both Empower Pharmacy's "dedication to improving compliance," and "sustained compliance," and yet, it is unclear whether LegitScript ever even considered Empower for probationary certification. In previous application cycles, Empower Pharmacy raised the possibility of being granted probationary certification from LegitScript, but LegitScript did not engage substantively with Empower Pharmacy with regards to this option.

174. It is also notable that LegitScript apparently has a different pricing structure for probationary certification, with probationary certification "typically cost[ing] more than standard certification." Ex. 14 at 2; *see* Ex. 7 at 4 ("probationary certification pricing will be determined on a case-by-case basis").

175. Furthermore, as noted above, LegitScript has also represented to Empower's customers that it is willing to "work with applicants to ensure [they are] able to come into compliance" and that it "do[es] not frequently deny applications unless applicants are unwilling to come into compliance." Ex. 9 at 2. LegitScript requires applicants to "sufficiently remediate[] to LegitScript's satisfaction"—however, LegitScript has failed to provide any guidance on what "sufficient[] remediat[ion]" entails and how applicants may achieve it. Ex. 7 at 4.

176. LegitScript's repeated denial of certification without meaningfully explaining the basis for those denials, refusal to provide guidance as to the standard it has been applying to Empower's applications or how to become certified, and its imposition of a six-month waiting period all support the conclusion that LegitScript has unreasonably and arbitrarily enforced its certification standards, particularly when its certification of other entities is taken into consideration. When taking a step back and observing how LegitScript has applied its certification standards to other pharmacies seeking Healthcare Merchant Certification, the discriminatory nature of LegitScript's conduct becomes apparent.

B. In Stark Contrast to LegitScript's Arbitrary and Biased Treatment of Empower, LegitScript Has Certified Entities with Far More Serious Regulatory and Legal Violations.

177. For example, one compounding pharmacy that LegitScript certified, on information and belief in early 2023, has a Form 483 on file from March 14, 2022, and a Warning Letter from April 1, 2020—neither of which were closed out by the FDA prior to LegitScript Certification. Significantly, LegitScript granted certification to this entity despite even more serious issues from October 2020, when this entity and its owner ***pled guilty to the unlawful distribution of unapproved compounded prescription drugs throughout the United States from October 2018 through April 2020***.[30] Specifically, the compounding pharmacy and its owner pleaded guilty to the unlawful distribution of selective androgen receptor modulators ("SARMS") and other substances the FDA had not approved for distribution in the United States, including unapproved new drugs. In connection with the plea, the pharmacy and its owner agreed to forfeit more than

[30] *See* Press Release, U.S. Dep't of Just., Nicholasville Compounding Pharmacy and Its Owner Plead Guilty to Unlawful Distribution of Prescription Drugs (Oct. 29, 2020), available at: https://www.justice.gov/usao-edky/pr/nicholasville-compounding-pharmacy-and-its-owner-sentenced-unlawful-distribution.

$1.7 million, representing its 2019 sales for the products. The owner and CEO of the pharmacy pled guilty to having knowingly caused its pharmacy to fill and ship bulk, wholesale distributions of Methylcobalamin to a doctor, knowing that the pharmacy had never applied for permission from the Kentucky Board of Pharmacy to act as a wholesale distributor of prescription drugs. The pharmacy additionally had a voluntary recall of products in 2018 due to incorrect beyond use dates on vial labels. Nevertheless, despite these serious issues, LegitScript certified this entity and has not revoked its certification to this day. Yet soon after LegitScript *granted* certification to this pharmacy despite having pled guilty to serious legal violations, it *denied* Empower's certification despite having acknowledged Empower's "dedication to improving compliance."

178. Even more recently, in January 2025, LegitScript granted certification to a 503B outsourcing facility that received an FDA-issued Warning Letter in 2021 and multiple Form 483s in 2019, 2022, and 2024, none of which have been followed by a "closeout" letter from the FDA. Notably, the FDA observed in the 2021 Warning Letter to this facility that it "[did] not have any FDA-approved applications on file for drug products that [it] compound[ed]" and that it "compound[ed] drug products that are intended for conditions not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses causing them to be misbranded under section 502(f)(1) of the FDCA." These observations are similar to the FDA's observations in the 2021 Warning Letter LegitScript cited as grounds for denying Empower's application. Despite unresolved FDA regulatory activity, LegitScript nonetheless granted Empower's competitor its certification.

179. LegitScript also certified another entity on October 25, 2024 despite it having multiple Form 483s on file, dated April 2018, March 2022, and May 2024—all issued and unresolved prior to obtaining its LegitScript Certification. The FDA observed in March 2022 in a Form 483 that this "outsourcing facility compounds drug products using bulk drug substances that cannot be used in compounding under section 503B because they (a) have been identified in a federal register notice as not being placed on the 503B Bulk List and do not appear on the drug shortage list in effect under section 506E of the Act or (b) appear on the 503B Category 2 (bulk drug substances identified by FDA as presenting significant safety risk)." None of this entity's Form 483s were closed out by the FDA, but unlike LegitScript's refusal to grant Empower its certification due to purportedly unresolved regulatory issues, LegitScript turned a blind eye to this entity's Form 483s and instead granted certification.

180. Additionally, LegitScript certified another pharmacy, upon information and belief sometime between October 2021 and December 2021, despite having an open Form 483 from October 2020. Since 2021, the FDA further issued this pharmacy another Form 483 in September 2022 and a Warning Letter in September 2023. Evidently, the open regulatory issues neither prevented LegitScript from certifying this pharmacy nor warranted the revocation of its certification.

181. Furthermore, at least one compounding pharmacy remains LegitScript-certified despite having entered into a consent agreement and having been ordered by a state board of pharmacy to pay a fine for allegedly violating state law. This same pharmacy, moreover, has also been the subject of another complaint by a different state for selling "misbranded drugs in violation of both state and federal law" and taking "illegal actions" that "pose significant risks and dangers" to consumers, including by marketing certain peptides that the FDA has banned for

raising "significant safety risks." At least three additional LegitScript-certified pharmacies have likewise been the subject of state complaints for selling illegal peptides after the FDA banned them. Under LegitScript's standards, "[m]erchants must be adequately licensed for the services they offer and in the jurisdictions they serve." Moreover, LegitScript's standards state that "[t]he applicant must comply with all provisions of applicable laws and regulations," and "must not facilitate the prescribing or dispensing of medications that do not hold the necessary authorization or approval from the applicable regulatory body in that jurisdiction or medications that are otherwise considered unapproved by relevant regulatory bodies." If LegitScript were consistent and nonbiased in its application and enforcement of its certification standards, these compounding pharmacies should have lost their LegitScript Certifications—but did not.

182. In addition to the LegitScript-certified compounding pharmacies listed above that were certified despite having unresolved "disciplinary actions"—as defined by LegitScript's Terms and Conditions—on file, there are many compounding pharmacies that have retained their LegitScript Certification without issue after being issued a Form 483 by the FDA, including at least five additional pharmacies beyond those referenced above.

183. LegitScript's pattern of granting certification to pharmacies that have had extremely serious regulatory issues, unlike Empower, demonstrates a biased and discriminatory application of its standards to the competitive disadvantage of Empower.

184. Empower Pharmacy is still not LegitScript certified. It is difficult to reconcile LegitScript's reasoning for denying Empower's application for certification with LegitScript's certification of other compounding pharmacies. LegitScript's arbitrary, biased, and discriminatory application of its certification standards has competitively disadvantaged

Empower and has substantially foreclosed its access to key customers, relationships, and distribution channels it needs to compete against LegitScript-certified competitors.

C. LegitScript's Imposition of an Arbitrary Waiting Period Before Permitting Empower to Reapply for Certification Was Biased and Discriminatory.

185. Empower sought to mitigate the negative impact of LegitScript's enforcement of its "Affiliates" rule by applying for a LegitScript Healthcare Merchant Certification for its 503A Pharmacy (Empower Pharmacy). Despite seeking to satisfy all of LegitScript's requests, LegitScript has unreasonably and discriminatorily withheld certification from Empower.

186. Following LegitScript's denial of Empower's application for certification on or around June 24, 2024, LegitScript arbitrarily imposed a "mandatory" six-month waiting period—expiring on December 24, 2024—before Empower was permitted to reapply for certification. Ex. 12 at 1. Contrary to LegitScript's acknowledgement of Empower's "dedication to improving compliance," LegitScript imposed a waiting period it purported to be "essential to allow adequate time to demonstrate ***sustained compliance*** with [its] Certification Standards*."* *Id*. (emphasis added).

187. LegitScript's imposition of a six-month waiting period on Empower Pharmacy cannot be anything but arbitrary and biased. LegitScript's indication that the waiting period was to allow Empower Pharmacy to "demonstrate sustained compliance" with LegitScript's standards suggests that Empower Pharmacy had already come into compliance with LegitScript's certification standards. The imposition of a waiting period was also arbitrary given that LegitScript awards "probationary certification" status to other applicants that "require increased monitoring and review." *See* Ex. 7 at 4.

188. Notably, this waiting period also coincided with the time needed for a large pharmaceutical competitor with which LegitScript has close ties through membership in ASOP to remove its GLP-1 medication from the FDA shortages list.

189. The expiration date of the waiting period (December 24, 2024) also corresponded to Ro's announcement of its partnership to distribute tirzepatide through its telemedicine service for the same large pharmaceutical competitor with which LegitScript has close ties through ASOP.

190. LegitScript's arbitrary and biased imposition of a six-month waiting period on Empower has directly impacted its ability to combat LegitScript's aggressive and unreasonable enforcement of its "Affiliates" rule. In the time since LegitScript imposed this waiting period, LegitScript has continued to characterize a business relationship with Empower as a barrier to certification. In turn, Empower's customers have been coerced into dropping Empower as a supplier.

191. Accordingly, LegitScript's most recent denial of Empower's application for certification and its arbitrary application of an atypical waiting period appears strategically imposed to buy time for Empower's competitors to be able to sell competitive GLP-1 medications and to prevent Empower from solidifying and growing its relationships with customers during the time its competitors were unable to satisfy the market's demand for GLP-1 medications or to more efficiently supply those customers through a distributor that can compete more directly against Empower for sales.

D. LegitScript's Website Classification Guide is Arbitrary and Its Classification of Empower as "Unapproved" Is Further Evidence of LegitScript's Discriminatory and Anticompetitive Practices

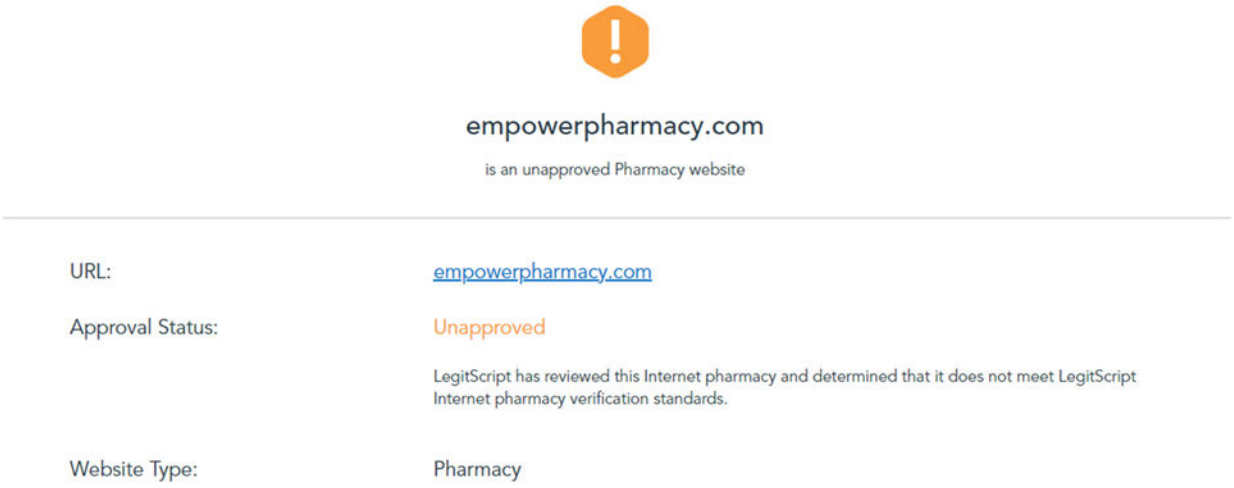
192. LegitScript has used its power over the relevant markets to enforce a set of arbitrary "legitimacy classification[s]," which have served as barriers to entry and competition due to the effect these classifications have on the pharmacy's reputation. LegitScript has further classified pharmaceutical merchants in a biased and discriminatory manner by overlooking blatant regulatory violations and labeling problematic pharmaceutical merchants as "legitimate" or "certified."

193. LegitScript changed its website classifications system in early 2022 and added a fifth category to its Website Classification Guide—"certified"—which was a unique category for pharmaceutical merchants who were specifically LegitScript-certified. Prior to this change, there were only four categories: "Rogue," "Unapproved," "Unverified," and "Legitimate." The definitions for "Rogue," "Unapproved," and "Unverified" have largely stayed the same; however, "Legitimate" used to be "available only to merchants and websites eligible for one of LegitScript's certification programs (currently online pharmacies and eyewear)" that "passed LegitScript Certification criteria." Now, the "Legitimate" label is reserved for "website[s] [that are] not LegitScript-certified, but [have] received accreditation or certification from other entities that LegitScript recognizes, such as the NABP." LegitScript provides no guidance on its website or otherwise on what other types of "accreditation or certification from other entities" it recognizes. Also, as previously mentioned, the new "Certified" label is reserved for "website[s] [that are] LegitScript-certified, meaning it has been vetted through LegitScript's rigorous review processes and is monitored on an ongoing basis."

194. Notably, this change was done around the same time the FDA placed semaglutide injections, Ozempic® and Wegovy®, on the shortage list.

195. LegitScript asserts that its "core principle" in categorizing pharmaceutical merchants is that "the merchant should comply with laws and regulations where it is located, as well as the laws and regulations in each jurisdiction where it serves its customers." Yet, LegitScript classifies pharmacies with extensive regulatory issues and multiple violations on record as a "legitimate" pharmacy, and indeed has certified some compounding pharmacies despite unresolved FDA violations and even guilty pleas for violations of law, as discussed above.

196. In contrast, however, LegitScript classifies Empower as "Unapproved," thereby harming its reputation and placing it at a competitive disadvantage vis-à-vis its competitors without a legitimate reason for doing so. LegitScript has given Empower this "Unapproved" designation despite the fact that Empower "compl[ies] with the laws and regulations where it is located," as LegitScript requires, and complies with "the laws and regulations in each jurisdiction where it serves customers." Furthermore, Empower Pharmacy is PCAB-accredited, which, by LegitScript's own standards should grant it "Legitimate" status because it has "received accreditation or certification from other entities."



197. On the other hand, LegitScript classifies a major retail pharmacy as "legitimate" based on its Healthcare Merchant Certification on LegitScript's website even though it has paid over $40 million in fines as a result of a series of investigations by the Drug Enforcement Administration and the Department of Justice and, in May 2008, paid $36.7 million to settle allegations that it defrauded the government by improperly switching patients taking generic Zantac to capsules from the tablet form of the heartburn drug. In 2015, this reportedly "legitimate" retail pharmacy was also fined $22 million by the DEA after the pharmacy admitted that its pharmacists knowingly distributed controlled substances (pain killers) based on prescriptions that had not been issued for legitimate medical purposes by a health care provider. Nevertheless, this pharmacy remains classified as "legitimate" despite the fact that as recently as December 2024, the DOJ filed a nationwide lawsuit alleging that the pharmacy and its various subsidiaries knowingly dispensed controlled substances in violation of the Controlled Substances Act ("CSA") and the False Claims Act ("FCA").

198. As another example of LegitScript's biased and discriminatory certification and classification standards, LegitScript publicizes on its website that another major retail pharmacy

is "certified" and that "LegitScript has reviewed this website or merchant as part of our certification program and has determined that it meets our standards for legality, safety and transparency!" LegitScript further advises, "That means we monitor this merchant regularly." However, LegitScript has not revoked this pharmacy's certification despite the pharmacy being sued by the Department of Justice in January 2025 for allegedly dispensing millions of unlawful prescriptions in violation of the CSA and FSA. The DOJ's complaint alleges that the pharmacy "knowingly" filled prescriptions for controlled substances that "lacked a legitimate medical purpose, were not valid, and/or were not issued in the usual course of professional practice" from August 2012 to the present resulting in patients dying from overdose deaths shortly after getting invalid prescriptions filled at the pharmacy. The DOJ alleges that the pharmacy prioritized "profit over patient safety," alleging that its "pharmacists filled these prescriptions despite clear 'red flags' that indicated that the prescriptions were highly likely to be unlawful … ignor[ing] substantial evidence from multiple sources that its stores were dispensing unlawful prescriptions." The DOJ further alleged that the pharmacy "systematically pressured its pharmacists to fill prescriptions quickly without taking the time needed to confirm each prescription's validity" and "deprived its pharmacists of crucial information" necessary to verify the legitimacy of each prescription it filled. Yet, this pharmacy remains LegitScript certified, despite LegitScript publicizing that it regularly monitors this pharmacy and that it meets LegitScript standards for "legality" and "safety." When confronted with the blatantly discriminatory treatment of entities that have remained certified despite serious regulatory enforcement actions, John Horton argued that there was a "straightforward difference" between its disparagement of its competitors and its treatment of an entity that remains certified in that

the entity's "business strategy isn't predicated on operating illegally" and did not have an "*entire* business plan [that] centers around *continuous* illegal conduct."[31]

199. While John Horton acknowledged that the behavior of its certified pharmacy "shouldn't be overlooked," he stressed that "it doesn't follow that [the pharmacy's] *fundamental business plan* relies on *ongoing* illegality." He further noted that if other "pharmacies wanted to start operating legally … we'll classify them as legitimate."[32] Nevertheless, LegitScript publicly disparages Empower as an "Unapproved" pharmacy on the purported basis that Empower does not meet its certification standards for safety and compliance while it simultaneously touts the "safety" and "legality" of pharmacies that have pled guilty or admitted to serious violations of law relating to their pharmacy practices or are currently defending government enforcement actions charging them with serious violations of law that the government alleges have resulted in patient deaths.

200. Notably, Empower is not the first entity that poses a competitive threat to LegitScript-certified entities that has been the target of "LegitScript's false and misleading accusations." In 2017, for example, the General Manager of the Canadian International Pharmacy Association ("CIPA") wrote an article in response to "an inaccurate and misleading critique" of its business that "was clearly intended to smear [its] reputation with a broad brush dipped in inaccuracies and scare tactics." CIPA's General Manager noted that "despite CIPA's strict safety procedures and 100% perfect safety record, LegitScript is trying to falsely paint us into the 'rogues' corner of the web" as a result of it "shining a spotlight on the U.S.

[31] John Horton, *EFF's Emerging Alignment with Offshore Internet Pharmacies*, CircleID (Mar. 21, 2017), https://circleid.com/posts/20170321_eff_emerging_alignment_with_offshore_internet_pharmacies#11681 (including comment chain between John Horton, President of LegitScript, Gabriel Levitt, President of PharmacyChecker, and Jeremy Malcolm) (emphasis added).
[32] *Id.* (emphasis added).

pharmaceutical industry's coordinated campaign to eliminate threats." He noted that this "is what appears to have motivated LegitScript to campaign to suppress consumer choice and competition under the false pretense of protecting consumers." He further discussed his and others' "concerns about private interests promulgating standards for key Internet intermediaries designed to serve their own financial interests" and stated that "[w]hile LegitScript hurls unfounded accusations at CIPA, they should take a second look … at the U.S. pharmacies it claims are 'legitimate' and the pharmaceutical companies that are funding misleading campaigns with similar themes as those presented by LegitScript and its affiliates."[33]

III. LegitScript's Conduct Has Harmed, and Continues to Harm, Competition in the Relevant Markets, Empower, Empower's Customers, Patients, and LegitScript's Competitors.

A. LegitScript's Unlawful Conduct Has Harmed the Competitive Process and Competition on the Merits.

201. LegitScript's unlawful conduct has distorted and harmed the competitive process and competition on the merits of competitors' products, quality, services, and prices that would otherwise prevail in a competitive market. Rather than providing compounding customers and patients with reliable information that could better inform their purchasing choices, LegitScript has introduced false and disparaging information into the market based on biased and discriminatory interpretations of sham standards that distort and restrain free and fair competition. Beyond merely distorting market dynamics with false and misleading information, LegitScript has further abused its market power by coercing customers to cut ties with suppliers with which they would have preferred to do business absent LegitScript's anticompetitive

[33] Tim Smith, *The Broad Brush of LegitScript, Painting Inaccuracies About CIPA*, CircleID (Apr. 18, 2017), https://circleid.com/posts/20170418_broad_brush_of_legitscript_painting_inaccuracies_about_cipa.

coercion. In doing so, LegitScript has further distorted competition on the merits for competitive certifications because certifications that are not accepted by LegitScript no longer enhance their certified entities' ability to sell to customers that are seeking a LegitScript certification or that are already LegitScript-certified.

B. LegitScript's Unlawful Conduct Has Caused Actual Adverse Effects on the Market, Harming Compounding Customers and Patients.

202. LegitScript's unlawful conduct has disrupted supply arrangements and relationships during FDA-recognized national shortages of GLP-1 medications, such as semaglutide and tirzepatide. At a time when an extraordinary increase in demand far outstripped the available supply, LegitScript coerced Empower's customers to cut off one of their sources capable of compounding these high-demand medications. Given the extraordinary demand for these medications during a time when supply was already capacity-constrained, cutting Empower off from customers and distribution channels for these medications resulted in a restriction of output. Given the difficulty in finding alternative sources of supply during the national shortage, moreover, the disruption in the supply relationship itself restrained and reduced the output that otherwise would have prevailed in a competitive market absent LegitScript's interference.

203. Empower's pricing for compounded GLP-1 medications, moreover, is generally far lower than brand competitors' pricing and often lower than the pricing of other competitors, such as those selling GLP-1 medications under a subscription model that imposes additional fees above and in addition to the cost of the products themselves. Ro, for example, advertises the availability of branded semaglutide for $900-$1,000 monthly, on top of which a subscriber must

pay Ro a $145 monthly membership fee, for a monthly total of $1,045-$1,145.[34] Branded semaglutide, moreover, is reported to have an even higher manufacturer list price of $1,350.[35] In contrast, even without factoring [redacted], Empower sells compounded semaglutide at list prices for roughly $[redacted].

204. Empower's prices are also frequently lower than its direct compounding competitors as well. For example, [redacted]

205. Accordingly, customers, and in turn patients, who were forced to find another source for GLP-1 medications once LegitScript restrained their ability to purchase from Empower were further harmed not only by the disruption in their supply of these medications but also because they then had to pay higher, and thus supracompetitive, prices than they would have otherwise paid in a competitive market had they remained free to purchase GLP-1 medications from Empower.

206. Patients using compounded products that are tailored to their unique needs have additionally been harmed, regardless of whether the specialized products they need are altered variations of GLP-1 medications. Patients who were blocked by LegitScript from accessing specifically tailored variations of GLP-1 medications from compounding pharmacies that are not certified by LegitScript may have lost all access to a source that could provide medically

[34] *See* Ro Weight Loss Pricing, Ro.co, *https://ro.co/weight-loss/pricing/* (last visited Mar. 22, 2025).
[35] *See How Much Does Zepbound (Tirzepatide) Cost Without Insurance?*, GoodRx, https://www.goodrx.com/zepbound/weight-loss-tirzepatide-cost (last visited Mar. 22, 2025).

appropriate GLP-1 medications as a result of LegitScript's conduct. However, patients who were receiving specialized products for other treatments likewise may have lost access to medically appropriate versions of products they needed, at least temporarily, as a result of the disruption caused by LegitScript. Indeed, given the extraordinary demand for compounded GLP-1 medications during this time, the availability of other compounded medications that needed to be specifically tailored to a patient's unique needs were already largely capacity constrained, only to be further restricted to those compounding pharmacies that were already LegitScript-certified.

207. Patients of tirzepatide have shared their concerns with losing the option to purchase compounded tirzepatide, noting that they are "devastated that this option [(compounded tirzepatide)] is going away."[36] These worries are not unfounded, as after the timeline for pharmacies to stop making compounded versions of tirzepatide expires, the "only version available will be the FDA-approved, pricier type." "For patients, this all adds up to a lot of confusion, changes, and, potentially, interruptions in treatment. The transition period will not be seamless."[37]

208. Empower's customers have also been harmed by LegitScript's unlawful conduct because those providers have needed to seek other, less efficient 503B facilities to source compounded products for their patients. LegitScript's "Affiliates" rule prohibiting Empower's customers from working with Empower due to its lack of LegitScript Certification forces Empower's customers to expend additional costs to locate and source from LegitScript-certified

[36] Emily Stewart, *See ya, Knock-off Ozempic*, Bus. Insider (Jan. 22, 2025), https://www.businessinsider.com/fda-compounded-tirzepatide-semaglutide-shortage-ozempic-2025-1.
[37] *Id.*

503B outsourcing facilities. Even then, the providers' newly chosen 503B outsourcing facility may not ship nationwide (as Empower does), meaning those clinics and providers then have to consolidate orders piecemeal across various pharmacy vendors. This is less efficient, as providers then need to invest in methods to standardize the labeling and appearance of the products and invest in procedures to ensure that each 503B facility conforms with state and federal laws.

C. LegitScript's Unlawful Conduct Has Harmed Empower.

209. LegitScript's unlawful conduct has directly and proximately caused Empower to suffer millions of dollars of damages as a result of LegitScript coercing customers to stop doing business with Empower, its commercial disparagement of Empower, and its implementation and enforcement of anticompetitive rules prohibiting LegitScript-certified entities from purchasing from entities like Empower that are not LegitScript-certified. As a result of LegitScript's violations of law, Empower has lost customers, business opportunities, customer good will, and profits.

210. LegitScript's anticompetitive conduct has specifically caused harm to Empower Pharmacy's business. Empower Pharmacy, operating under Section 503A of the FD&C Act, specializes in compounding patient-specific medications tailored to individual needs. LegitScript's anticompetitive conduct, however, has impeded Empower Pharmacy's ability to conduct its day-to-day operations and serve patients who have specific needs. LegitScript's anticompetitive conduct—the unreasonable enforcement of its "Affiliates" rule—has limited this growth and threatened competition in the market for compounded, patient-specific drugs. As a result of LegitScript's anticompetitive conduct, LegitScript-certified healthcare providers, or those seeking LegitScript Certification, are unable to access Empower Pharmacy as a partner

pharmacy for patient-specific drugs. Empower Pharmacy, despite being a legitimate compounding pharmacy authorized to conduct business under the relevant state and federal laws, has found itself unable to access an entire segment of its customer base, severely impacting its overall business.

211. LegitScript's anticompetitive conduct has likewise caused harm specifically to Empower Pharma's business. Empower Pharma is in the business of compounding, selling, and distributing a wide variety of products that treat an assortment of conditions. Empower Pharma's business depends on its ability to enter into business relationships with healthcare providers and pharmacies, but LegitScript's conduct has directly impeded its ability to access these distribution channels. As a direct result of LegitScript's communications with Empower's customers, for example, numerous customers that had been using Empower Pharma as their outsourcing facility stopped doing business with Empower. Likewise, as a direct result of LegitScript's communications with Empower's customers, numerous prospective customers of Empower Pharma excluded the possibility of a business relationship with Empower Pharma. The overall effect of LegitScript's anticompetitive conduct on Empower Pharma has not only resulted in lost revenues for Empower Pharma, but has also harmed Empower Pharma's ability to continue to grow and invest in additional areas of business such as testing services in support of clinical trials. In February 2024, Empower Pharma acquired a compounding facility in East Windsor, New Jersey, adding a second outsourcing facility to its business. The acquisition marked Empower Pharma's second FDA-registered pharmaceutical site. With the acquisition, Empower Pharma expanded its compounding capabilities and aimed to produce up to 110 million vials annually as well as engage in testing services in support of clinical trials. Empower Pharma's substantial investment, however, is being threatened by LegitScript's anticompetitive conduct.

LegitScript's unlawful conduct has already caused—and, if not corrected, will continue to cause—Empower Pharma to be substantially foreclosed from the distribution channels to which it would otherwise have access.

IV. LegitScript's Anticompetitive Conduct Has Harmed Competition in Several Relevant Markets

212. There are several antitrust markets that are relevant to understanding and evaluating LegitScript's anticompetitive conduct: (1) the market for certification of healthcare providers and pharmaceutical service providers with an online presence (the "certification market" or "tying market"); (2) the market for the manufacturing and sale of compounded products ("compounding market"), including relevant markets (a) for the sale of compounded products that are personalized or tailored to a patient's specific needs; (b) for the sale of compounded prescription products by outsourcing facilities for administration by providers in their healthcare facilities (e.g., by hospitals); and (c) for the sale of prescription medications during periods of shortages as identified by the FDA; and (3) product markets for the various products that are compounded, which are set forth herein as "cluster markets" for analytic convenience and include, for example, (a) the market for GLP-1s; (b) the market for hormone replacement therapy or "HRT" treatments; (c) the market for sexual dysfunction treatments; (d) the market for dermatological products and treatments; (e) the market for fertility treatments; (f) the market for mental health products; and (g) the market for longevity and anti-aging products.[38]

[38] *See* U.S. Dep't of Justice, 2023 Merger Guidelines, available at: https://www.justice.gov/atr/merger-guidelines/tools/market-definition.

A. The Market for Certification of Healthcare Providers and Pharmaceutical Service Providers with an Online Presence Is Highly Concentrated and Controlled by LegitScript.

213. The market for certification or accreditation of telemedicine providers, online pharmacies, 503A compounding pharmacies and 503B outsourcing facilities encompasses various accreditation organizations that individually vet applicants based on set standards and grant a "seal of approval" to applicants they determine meet those stated standards.

214. Industry participants recognize online pharmacy "verification," "certification," or "accreditation" as a unique market.[39] PharmacyChecker.com, a competitor in this area, has itself defined online pharmacy verification as a distinct and highly concentrated market in which it competes with NABP, LegitScript, and CIPA. CIPA, however, is a trade association of Canadian pharmacies and only certifies Canadian websites that comply with Canadian laws and thus is not a viable certification option for Empower or its U.S. customers. PharmacyChecker.com likewise is no longer a viable certification option because, as it has alleged in its own antitrust litigation against LegitScript, NABP, ASOP and others, it "has now effectively been excluded from the market as a result of defendants' shadow regulation."

215. As a result of the web of agreements LegitScript has now entered into with the leading search engine and social media platforms, some of which specifically require a LegitScript Certification (and will not accept an NABP certification as a substitute) for online pharmacies to advertise on their platforms, LegitScript is the only certification option for these entities to gain access to the advertising channels they need to compete. As a digital marketing

[39] Generally, the term "online pharmacy … means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet." 21 U.S.C. § 802(52)(A).

company serving the healthcare industry notes, "if you are prescribing medication of any kind at your facility, you have to have LegitScripts to be able to market through search engines. Period, end of story, [it] is a must-have. Google, [a leading social media platform], [and] all of the online markets will shut down any paid advertisements that you have if you are not LegitScript certified. … [S]o long as you are marketing online, whether you are a brick-or-mortar or a purely online business, it is important and absolutely a requirement—a mandatory requirement—that you have LegitScripts." *See also* Ex. 16 (identifying additional platforms, payers, and companies that use LegitScript).

216. LegitScript initially derived its power in the certification market from its agreements with major search engines and social media platforms that have resulted in LegitScript becoming the gatekeeper for telemedicine providers and online pharmacies seeking to advertise online. For example, LegitScript's marketing on its website advertises its Healthcare Certification Partners, listing Google, social media platforms, video streaming websites, and an established professional networking platform all as "strategic partners."[40] Google and social media platforms that are critical to the competitive success of Empower's customers, by way of their partnerships with LegitScript, have effectively delegated to LegitScript the power to decide who may or may not display ads on their respective platforms.

217. For example, Google's ad policy permits telemedicine providers to advertise on its search engine only "if they are accredited by LegitScript's Healthcare Merchant Certification Program."

[40] LegitScript Certification: Strategic Partners, LegitScript, https://www.legitscript.com/certification/strategic-partners/ (last visited Mar. 22, 2025).

218. Similarly, a leading social media platform that operates multiple social media websites and applications, requires pharmaceutical manufacturers, online pharmacies, and telemedicine providers to obtain a LegitScript Certification prior to advertising on its platforms and does not recognize an NABP certification.

219. In addition to search engine and social media platforms, YouTube also requires a LegitScript Certification for telemedicine providers seeking to advertise on its platform.

220. An established professional networking website allows pharmacy and telehealth service providers to place ads on its website but only when they originate from LegitScript-certified or NABP-accredited advertisers; the platform then provides a link only to LegitScript's certification page. Users are not directed to visit the NABP website.

221. Although online pharmacy and telemedicine providers may seek a NABP certification, LegitScript Certification, or both, an NABP certification is accordingly not a viable substitute for a LegitScript Certification. In practice, for telemedicine providers, LegitScript's Healthcare Merchant Certification is the only certification that various leading platforms will accept prior to allowing them to advertise on their respective platforms. As noted by one publication, "[w]hile the … NABP is also recognized by some platforms, LegitScript is the more common choice for digital health brands due to its streamlined process and broader acceptance."[41]

222. LegitScript itself has recognized a distinction between its own certification and an NABP certification. For example, LegitScript's website classification system recognizes its own certification as separate and distinct from a NABP certification. A website that is NABP-certified

[41] *LegitScript Certification For Health Marketing: Everything You Need To Know*, 360 OM, https://www.360om.agency/news-insights/legitscript-certification-for-health-marketing-everything-you-need-to-know (last visited Mar. 22, 2025).

but not LegitScript-certified would be classified merely as "Legitimate." The only way for a website to earn the "Certified" classification is to go through LegitScript's certification process.

223. LegitScript's increasingly aggressive enforcement of anticompetitive rules prohibiting applicants and LegitScript-certified entities from purchasing products from entities that are not LegitScript-certified, in turn, further reduces certification options to itself alone for entities such as Empower whose business depends upon maintaining access to their online pharmacy customers, which already require LegitScript's certification to meaningfully compete online. While Empower already is PCAB-accredited, due to LegitScript's unlawful and anticompetitive conduct, PCAB accreditation is not a reasonable substitute for LegitScript's Healthcare Merchant Certification because only LegitScript's certification can now maintain and otherwise provide access to the telemedicine and online pharmacy customer relationships that Empower needs to compete in the relevant markets further set forth below. LegitScript is thus increasingly using this web of agreements to maintain and extend its monopoly power in the certification market by excluding competitors, such as PharmacyChecker.com, from the certification market and excluding competitors to LegitScript-certified entities from the market for the supply of medicines to the entities that need or already have a LegitScript Certification.

224. LegitScript offers three (3) different certification programs depending on the nature of the applicant's business: Healthcare Merchant Certification, Addiction Treatment Certification, and CBD Certification. As a provider of healthcare services, Empower and its competitors have sought or would seek a Healthcare Merchant Certification, which purports to "vet pharmacies, telemedicine providers, telehealth providers, other healthcare providers, and supply chain businesses including pharmaceutical manufacturers, wholesalers, and

distributors."[42] According to LegitScript, its Healthcare Merchant Certification program purportedly distinguishes between "'rogue' internet pharmacies" that "expose consumers to danger" and are "operating with flagrant disregard for the law" and "legitimate pharmacies trying to reach patients in need."

225. Applicants for LegitScript's Healthcare Merchant Certification are required to pay a nonrefundable, one-time application fee and, once certified, an annual certification fee per website. As of February 2020, the one-time application fee per website was $975, while the annual fee per website was $2,150.[43]

226. On information and belief, payments LegitScript receives from entities with which it has agreements, such as Google and social media platforms, and other stakeholders in LegitScript's business, dwarf the remuneration it receives from certification applicants and bias LegitScript's certification and rule-making process. Rather than a unilateral and independent certification and rule-making process, these business partners have the ability to influence the outcome of application determinations and the imposition of rules LegitScript enforces, such as the "Affiliates" rule, to the detriment of competitors and free and fair competition.

227. To apply, applicants complete a questionnaire on LegitScript's website, which asks for information including, but not limited to, information about the applicant's business, licensing and registration, the applicant's website and/or mobile application, information about the applicant's partner pharmacy or pharmacies, and regulatory (e.g., FDA, DEA, state boards

[42] How to Get Your LegitScript Healthcare Merchant Certification, LegitScript, https://www.legitscript.com/healthcare/how-to-healthcare-certification/ (last visited Mar. 22, 2025) (providing "step-by-step instructions" for applicants of LegitScript's Healthcare Merchant Certification).

[43] *Id*.

of pharmacy) history. If certified, the applicant may display a badge on its website, indicating to visitors that it has obtained its LegitScript Healthcare Merchant Certification.

228. LegitScript is the only private service of that kind recognized by NABP. When LegitScript launched its Healthcare Merchant Certification in 2008, it became "the first endorsed by the National Association of Boards of Pharmacy." Ex. 13 at 3.

229. While NABP recognizes LegitScript, NABP itself also offers its own certification programs. Through NABP, telemedicine providers and online pharmacies may seek to obtain an Healthcare Merchant Accreditation which "ensures that merchants are properly licensed and follow applicable laws and business best practices."[44] NABP also maintains a program specific to online pharmacies; online pharmacies may choose to seek a NABP Digital Pharmacy Accreditation.[45] However, in contrast to NABP's Healthcare Merchant Accreditation and LegitScript's Healthcare Merchant Certification, NABP's Digital Pharmacy Accreditation is only available to *pharmacies* with "a website offering at least one interactive pharmacy practice component ([e.g.,] patient counseling/communication, new/refills/transfer prescription orders, patient/prescriber portals)."[46] Thus, telemedicine providers without "at least one interactive pharmacy practice component" are ineligible to apply for NABP's Digital Pharmacy Accreditation. In addition, although it is offered as a separate product, in order to obtain a NABP

[44] Healthcare Merchant Accreditation, Nat. Assoc. of Bds. of Pharm., https://nabp.pharmacy/programs/accreditations/healthcare-merchant/ (last visited Mar. 22, 2025).
[45] A precursor to the NABP's Digital Pharmacy Accreditation was the Verified Internet Pharmacy Practice Sites NABP ("VIPPS") program which, like the NABP Digital Pharmacy Accreditation evaluated and granted certain online pharmacy practice sites a seal of approval.
[46] Digital Pharmacy, Nat. Assoc. of Bds. of Pharm., https://nabp.pharmacy/programs/accreditations/healthcare-merchant/eligibility-requirements-and-standards/ (last visited Mar. 22, 2025).

Digital Pharmacy Accreditation, online pharmacies must first obtain a NABP Healthcare Merchant Certification.

230. LegitScript describes its certification services as "a recognized stamp of approval for the internet and payments companies that do business with … healthcare companies" (Ex. 13 at 3), and "a recognized seal of approval that enables businesses to showcase their compliance, unlock opportunities to advertise, and accept digital payments."[47]

231. LegitScript has erected high barriers to entry to the certification market as a result of the web of agreements it has entered with Google, a leading social media platform, Visa, and Mastercard,[48] as well as by prohibiting LegitScript-certified entities from purchasing products from entities that are not also LegitScript-certified. Having benefited from a first-mover advantage in the certification of online pharmacies and telemedicine providers, LegitScript now strengthens the barriers to entry due to network effects making it increasingly necessary to become certified by LegitScript regardless of whether its platform agreements identify LegitScript as the only acceptable certification.

232. In sum, because telemedicine providers, online pharmacies, healthcare merchants, Google, a dominant social media platform, YouTube, and others do not consider NABP, PCAB, or other certifications to be reasonable substitutes for LegitScript's Healthcare Merchant Certification given their varying characteristics, uses, and pricing, a small but significant increase in the price of LegitScript's Healthcare Merchant Certification and certification services from the competitive level would not be expected to cause entities seeking LegitScript's

[47] Certification, LegitScript, https://www.legitscript.com/certification/ (last visited Mar. 22, 2025).
[48] *See* Ex. 16 (listing entities with which LegitScript has agreements).

certification to switch to other certifications to an extent such as to have made those prices unprofitable.

B. LegitScript Has the Power to Exclude Healthcare Merchants, Telemedicine Providers, and Online Pharmacies from Access to Online Markets, Patients, and Relationships Needed to Compete.

233. LegitScript acknowledges that it has the power to deprive healthcare merchants more broadly from accessing basic tools needed to compete online. For example, LegitScript's website informs visitors that "LegitScript Certification helps ensure that merchants can fully participate in online advertising, e-commerce, and payment processing programs."[49]

234. In an August 14, 2023 press release, LegitScript reiterated the value of a LegitScript Certification for telemedicine providers, stating: "Nearly 80% of customers use online platforms to research healthcare providers, including pharmacies and telehealth. That makes online advertising a critical component of any healthcare provider's digital marketing strategy."[50]

235. A LegitScript blog post entitled "The Benefits of Each Certification for Your Business" published on LegitScript's website announced that "77% of patients use online search to find a new healthcare provider." According to the blog post, "Platforms Around the Globe Require LegitScript Certification to Unlock Advertising and Payment Processing."[51]

236. A Healthcare Certification Executive Summary published by LegitScript and available on the LegitScript website likewise acknowledged: "It's through search engines and social media that most patients are now finding their healthcare services."

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[49] LegitScript, Frequently Asked Questions, https://www.legitscript.com/certification/healthcare-certification/faq/ (last visited Mar. 22, 2025).

[50] Press Release, Business Wire, *LegitScript Certification Enables Advertising for Healthcare Businesses on LinkedIn* (Aug. 14, 2023), https://www.businesswire.com/news/home/20230814533977/en/LegitScript-Certification-Enables-Advertising-for-Healthcare-Businesses-on-LinkedIn.

[51] *Id*.

237. Based on the above, not only do telemedicine providers and online pharmacies rely on digital advertising to reach patients, but patients also rely on internet resources to find other healthcare and pharmacy providers as well.

238. In line with LegitScript's messaging, participants in the digital healthcare services space have also come to view obtaining a LegitScript Certification as an essential step in their overall marketing strategies. As a LegitScript-Certified entity noted in a testimonial published by LegitScript, "[m]ost people are now accessing information online, and through [LegitScript Certification], our company is using targeted marketing on online and digital spaces to reach our target audience." Ex. 13 at 18.

239. In an interview published to LegitScript's website, the CEO of a telehealth services provider and LegitScript-certified entity, stated: "For any business aiming to establish itself as a reputable digital care provider, obtaining LegitScript Certification is not just an industry standard ***but an essential requirement.***"[52] He also described "[o]btaining LegitScript Certification and establishing a partnership" as being "integral to our platform, enabling our clients to effectively advertise across all social media and advertising platforms."[53]

240. In another testimonial submitted by an online mail-order pharmacy, the company's co-founder stated: "Getting LegitScript-certified should be one of the first things a company does when they're looking to enter the digital health space***. LegitScript Certification is part of the core foundation upon which you can build telemedicine and telehealth infrastructure***."[54]

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[52] *Why Virtual Healthcare Service Provider WellSync Requires Its Network to Be LegitScript-certified*, LegitScript https://www.legitscript.com/customers/wellsync-requires-certification/ (last visited Mar. 22, 2025).

[53] *Id*.

[54] *Why did Epiq Scripts Choose LegitScript Certification?* LegitScript, https://www.legitscript.com/customers/epiq-scripts/ (last visited Mar. 22, 2025).

241. Similarly, a testimonial submitted by the co-founder and co-CEO of another LegitScript-Certified entity states: "LegitScript Certification … got us approved as advertisers on Google, [a leading social media platform], Taboola, and others. Without it, we would not be able to advertise on those platforms." Ex. 13 at 5.

242. LegitScript continues to market its services as a necessary step to being able to advertise on Google and social media platforms. On the other side of the same coin, the consequences of failing to obtain a LegitScript Certification are clearly announced by LegitScript; as LegitScript has noted, without certification, "***many banks, advertising programs, social media platforms, and ecommerce websites will terminate your account***."

243. Failure to obtain a LegitScript Certification likewise carries with it negative implications advanced by LegitScript via its online copy. For example, on LegitScript's website, LegitScript states that Google, social media platforms, Visa, and Mastercard, among other internet platforms, "all recognize LegitScript Certification to show the world their providers operate legally," thereby implying that the absence of a LegitScript Certification indicates non-compliance with applicable laws and regulations. Similarly, LegitScript's Healthcare Merchant Certification program purports to distinguish between "'rogue' internet pharmacies" that "expose consumers to danger" and are "operating with flagrant disregard for the law" from "legitimate pharmacies trying to reach patients in need," and its website prompts visitors to "enter a website to see if it is LegitScript-certified, legitimate, or rogue," suggesting that legitimate pharmacies that are not approved by LegitScript are instead illegitimate or rogue merely because they are not approved by this private entity that has sought to entitle itself to regulate the pharmaceutical market.

244. In carrying out its Merchant Healthcare Certification program, LegitScript retains the power to "grant, deny, or revoke [an applicant's] certification application or certification status for any reason and at any time." Ex. 7 at 4. Additionally, LegitScript "expressly reserves the right to refuse to consider any application." LegitScript's ability to turn applicants away—and therefore deny them access to vital digital marketing channels—results in LegitScript having enormous, coercive power over applicants seeking certification. That is, through its certification programs, LegitScript is able to impose any standards it so chooses onto applicants who have no meaningful choice but to comply if they wish to effectively participate in online advertising and marketing.

245. By making its Healthcare Merchant Certification a requirement for telemedicine providers and online pharmacies to advertise on Google and social media platforms, LegitScript has the power to deny legitimate telemedicine providers and online pharmacies access to online advertising and therefore severely stifle their ability to access and compete for patients.

246. In sum, LegitScript has become the monopoly gatekeeper between providers of online advertising and certain customers—i.e., between advertising providers, such as Google, social media platforms, YouTube, or other internet platforms, and a set of their customers seeking to advertise on those forums, including telemedicine providers, online pharmacies, and increasingly, other healthcare merchants whose business relies on sales to such customers. As has now been established in several antitrust proceedings, there are no close substitutes for advertising on platforms such as Google or other critical social medial platforms to which these customers could turn to satisfy their advertising needs.

C. The Market for the Manufacture and Sale of Compounded Products

247. The second relevant market in which to evaluate LegitScript's anticompetitive conduct is the market for the manufacture and sale of compounded products, which includes distinct market segments with unique economic characteristics (a) for the sale of compounded prescription products that are personalized or tailored to a patient's specific needs; (b) for the sale of compounded prescription products by outsourcing facilities for administration by providers in their healthcare facilities (e.g., by hospitals); and (c) for the sale of prescription products during periods of shortages as identified by the FDA. As set forth above in detail, the distinctions across these markets are delineated by a complex regulatory structure that dictates what compounded products can be manufactured at particular times under particular market conditions.

248. With respect to the sale of compounded prescription products that are personalized or tailored to a patient's specific needs, this market generally encompasses competition among compounding pharmacies to manufacture and sell products that are specifically tailored for an identified patient pursuant to preexisting prescriptions specific to particular patients. Sales in this market are generally made by competing 503A compounding pharmacies, which have a unique operational scope and regulatory framework compared to 503B outsourcing facilities. Patients need personalized products when brand manufacturers' products contain allergens, dyes, or other impurities or characteristics unsuitable for specific individuals. This necessitates the compounding of individually tailored products such that those individuals do not consider brand manufacturers' products to be reasonable substitutes given their varying characteristics. Therefore, a small but significant increase in the price of products that are compounded to suit a

patient's particular needs would not cause those patients or healthcare providers ordering products on their behalf to switch to branded or non-compounded products.

249. The evidence that compounding products constitutes a relevant antitrust market is clear from the price differential between branded and compounded products and the fact that while branded and compounded drugs are (at times and for some patients) substitutes, the primary constraint on the pricing of compounded drugs is competition from other compounders. In other words, a price increase by one compounder can be expected to induce switching to another compounder, whereas a further price increase on the branded product above the current level could be expected to shift patients toward compound drugs. Thus, compounded GLP-1 medications and branded GLP-1 medications each constitute a separate relevant market, but compounded and branded semaglutide or tirzepatide (or all GLP-1 medications) constitute a broader relevant market. As an example, if cars and pickup trucks are each a relevant market, but cars and pickup trucks are also substitutable, then cars and pickup trucks also constitute a broader relevant market such that a monopoly over both would be more profitable than two separate monopolies.

250. The market for the sale of compounded products by outsourcing facilities generally encompasses bulk or larger batch sales of compounded products requested by healthcare facility customers to have on hand to administer to patients in their medical facilities pursuant to prescriptions written by the doctors at those facilities, such as for pain management products or blood thinners, but may also include products compounded pursuant to a patient-specific prescription as well. This market generally comprises competing 503B outsourcing facilities and the products that may be compounded pursuant to an FDA-approved list of what ingredients may be used specifically by 503B outsourcing facilities to compound products as compared to

the distinct FDA-approved list of active ingredients that are permitted to be used by 503A compounding pharmacies. Thus, there are distinctions between both the products themselves and the customers of 503A compounding pharmacies and 503B outsourcing facilities governed by their distinct regulatory frameworks. Because healthcare facilities generally do not consider non-compounded products to be reasonable substitutes for various compounded products given their varying characteristics, uses, and pricing, a small but significant increase in the price of compounded products sold by outsourcing facilities would not cause healthcare facilities to switch significantly to alternative types of providers for those products.

251. The market for the sale of prescription products during periods of shortages as identified by the FDA encompasses the competition for the sale of products that are added by the FDA to the shortages list when the demand or projected demand for a drug within the United States exceeds the supply of the drug. When a drug is added to the FDA shortages list, the slightly varied restrictions on 503A compounding pharmacies and 503B outsourcing facilities on compounding essentially copies of an FDA-approved prescription drug are temporarily suspended, creating unique economic conditions in this market characterized by excess demand constrained by competitors' manufacturing capacities and ability to respond quickly to satisfy demand. Whereas there may be relative homogeneity among the types of entities competing in the compounding markets above, during shortages, the types of entities competing for sales of prescription drugs and essentially copies thereof, may expand to include not only compounding pharmacies, but also distributors selling products compounded by other entities, such as an entity like Ro, and brand manufacturers themselves.

252. As reported, the head of operations in the United States of the brand manufacturer of semaglutide stated on the fourth-quarter earnings call around early February 2025 that the

company's "latest market intelligence" indicated that competition from compounded versions of GLP-1 medications "is having an impact and it is growing faster than [the brand manufacturer] anticipated."[55]

253. However, where compounding pharmacies manufacture products that are specifically tailored to a patient's need to avoid ingredients in brand medications that are not medically appropriate then the market for the sale of those products will only include compounding manufacturers that are able to manufacture those specifically tailored products for the patient, even during national shortages.

D. Product Markets for Products That May Be Compounded

254. Various product markets for products that may be compounded are also relevant to the assessment of LegitScript's anticompetitive conduct. Given that LegitScript's anticompetitive and exclusionary conduct has impacted the sales of all of the types of compounded products that Empower previously sold to customers coerced by LegitScript to boycott Empower, products are clustered below for analytical convenience.

255. As the U.S. Department of Justice Merger Guidelines provide, "a relevant antitrust market is generally a group of products that are substitutes for each other … [however] … when the competitive conditions for multiple relevant markets are reasonably similar, it may be appropriate to aggregate the products in these markets into a 'cluster market' for analytic convenience, even though not all products in the cluster are substitutes for each other."[56] Courts

[55] Shelby Livingston, *Novo Nordisk is feeling the competition from compounded GLP-1s, exec says*, End Points News (Feb. 5, 2025), https://endpts.com/novo-nordisk-is-feeling-the-competition-from-compounded-glp-1s-exec-says/ (reporting that "many Americans have flocked to cheaper, compounded versions of GLP-1 weight loss drugs in lieu of brand-name treatments").
[56] U.S. Dep't of Just., Merger Guidelines 4.3.D.4, https://www.justice.gov/atr/merger-guidelines/tools/market-definition#.

have recognized that cluster markets may also be appropriate where consumer demand exists for the cluster itself (e.g., car and tires, left and right shoes), such as with respect to clustered product markets combining complementary prescription drugs, i.e., drugs that are not substitutes even if not all of the specific drugs within a cluster are close substitutes.

256. Barriers to entry and expansion in the relevant antitrust markets for the products below are high because entering these markets requires overcoming substantial capital, technical, regulatory, and legal barriers. The ability to enter and compete in these markets is highly regulated and, as set forth above, is subject to complex systems of federal and state regulations that delineate what competitors may manufacture what products containing what specific active ingredients and the timing permissible for such manufacturing under distinct market conditions.

257. LegitScript's exclusionary and unreasonably anticompetitive agreements have likewise created barriers to entry and expansion that are unlikely to be overcome without court intervention.

i. The Market for the Supply of GLP-1 Medications

258. GLP-1 medications consist of both GLP-1 agonists and dual GLP-1/GIP receptor agonists (together, "GLP-1 medications" or "GLP-1s").

259. The market for the supply of GLP-1 medications consists of manufacturers of brand-name medications supplied by the manufacturer and patient-specific and essentially copies of GLP-1 medications supplied by compounding pharmacies such as Empower that are available for sale, distribution, and consumption in the United States.

260. GLP-1 medications are manufactured and supplied for healthcare providers to prescribe to patients. Thus, this market encompasses GLP-1 medications prescribed to treat type 2 diabetes or as a weight loss treatment.

261. The market for the supply of GLP-1 medications includes all lawful sellers of the following GLP-1 agonist medications currently available in the United States market: duaglutide; exenatide; exenatide extended-release; liraglutide; lixisenatide; semaglutide injection; and semaglutide tablets. This market also includes tirzepatide, a dual GLP-1/GIP receptor agonist also prescribed to treat type 2 diabetes or as a weight loss treatment. The market for GLP-1 medications includes those administered subcutaneously (i.e., via injection), and the only GLP-1 medication currently available for oral administration: the semaglutide tablet.

262. Each specific GLP-1 medication constitutes its own market that is limited by the prescription written for the patient, such as for semaglutide injections or tirzepatide injections. However, there is also a cluster market more broadly for GLP-1s as a result of the extraordinary consumer demand that exists for the cluster itself, particularly during the national shortage of semaglutide and tirzepatide, when the very high prices for these drugs have increased consumers' willingness to substitute between the various GLP-1 drugs.

263. Healthcare providers enter into pharmacy provider agreements with manufacturers of GLP-1 medications for their supply of the drug or drugs. When a brand-name GLP-1 medication is not available—for example, due to a drug shortage caused by increased demand—healthcare providers may enter into pharmacy provider agreements with compounders who are legally authorized to manufacture patient-specific versions of GLP-1 medications and/or essentially copies of FDA-approved GLP-1 medications.

264. Patients may be willing to switch between alternative GLP-1 drugs in response to a significant change in their relative prices. However, as shown during the national shortages of semaglutide and tirzepatide, because consumers do not consider other weight-loss and/or diabetes medications to be reasonable substitutes for GLP-1 medications given their perceived

effectiveness, varying characteristics, and uses, a small but significant increase in the prices of GLP-1 medications as a group above current levels would not cause consumers or their healthcare providers to switch to other treatments for weight loss, diabetes, and other indications treated by GLP-1s.

265. Although it lacks any authority whatsoever to do so, LegitScript has inserted itself into the market for the manufacture and sale of compounded products, and relevant product markets for products that may be compounded, by determining which pharmacies are able to access key customers and distribution channels. For example, as discussed above, LegitScript has mandated that suppliers of GLP-1 medications must be LegitScript-certified in order to access LegitScript-certified healthcare providers and pharmacies needed to efficiently distribute those products.

266. While compounders and brand manufacturers compete for sales of essentially copies of GLP-1 medications, there is a unique market for the sale of GLP-1 medications that have been compounded to meet specific needs of patients for which branded GLP-1s are medically inappropriate.

267. Because commercial, brand-name products do not always meet patients' needs, 503A compounding pharmacies create individualized products to meet those needs. Thus, even when an FDA-approved drug (and its active ingredients) is not on the FDA-shortages list, pharmacies classified as 503A pharmacies under the FD&C Act are permitted to compound certain amounts of drugs that are essentially copies so long as the compounding is not done "regularly or in inordinate amounts." 21 U.S.C. § 353a. That is, by statute, "the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant

difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product." *Id*. at § 353a(b)(2).

268. For patients with specific needs as determined by their doctors, brand-name versions of tirzepatide or semaglutide are not suitable substitutes, as they cannot be specifically altered. Licensed compounders, on the other hand, have the legal authority to compound specifically altered versions of these GLP-1 medications when made in small quantities for identified individuals who have a valid prescription issued to them by a licensed healthcare provider.

269. As discussed above, separate markets for GLP-1 medications can also be defined for individual customers or periods for (a) GLP-1 medications tailored to specific patient needs; (b) compounded GLP-1 medications supplied to medical facilities; and (c) compounded GLP-1 medications manufactured as essentially copies during times of FDA-recognized supply shortages.

ii. The Market for the Supply of Hormone Replacement Therapy Drugs and Treatments

270. Hormone replacement therapy, sometimes referred to as "HRT," is a category of medical treatment used to "supplement the body with hormones that are no longer being produced or are produced in insufficient amounts."[57] While "commonly used to alleviate symptoms of menopause in women, such as hot flashes, night sweats, and mood swings … HRT can also be used for other hormone-related conditions or in transgender individuals undergoing gender-affirming hormone therapy."

[57] *Hormone Replacement Therapy (HRT)*, Yale Medicine, https://www.yalemedicine.org/clinical-keywords/hormone-replacement-therapy (last visited Mar. 22, 2025).

271. Hormone replacement therapy includes drugs and other treatments (i.e., topical treatments like gels and creams) that have the purpose of supplementing the body's production of the following hormones: adrenal, estrogen, growth hormone, progesterone, testosterone, and thyroid.

272. This market encompasses manufacturers—including compounders—of hormone therapy treatments. Manufacturers of hormone therapy replacement drugs and treatments participate in this market by entering into pharmacy partnership agreements with healthcare providers who treat hormone-related conditions, such as menopause.

273. Hormone replacement therapy drugs and treatments include, but are not limited to, the following drugs and treatments: anastrozole, estriol/estradiol medications and topical treatments, dehydroepiandrosterone ("DHEA") medications, hydrocortisone medications, progesterone treatments, testosterone treatments, thyroid treatments, oxandrolone medications, and pregnenolone medications.

274. Depending on the patient, healthcare providers may combine the various treatments available to treat symptoms caused by a reduced hormone production.

275. Because consumers do not consider other medications to be reasonable substitutes for compounded HRT medications given their varying characteristics, uses, and pricing structures, a small but significant increase in the price of HRT medications would not cause consumers to switch to other treatments.

iii. The Market for the Supply of Drugs and Treatments Targeting Sexual Dysfunction

276. The market for the supply of drugs and treatments targeting sexual dysfunction encompasses manufacturers—including compounders—who manufacture drugs and treatments for both men and women who experience sexual dysfunction. Sexual dysfunction disorders

encompass desire, arousal, orgasm, and pain disorders.[58] Thus, suppliers in this market manufacture drugs and treatments targeting disorders in the above-listed categories. At a more granular level, this could include manufacturers of treatments for erectile dysfunction, anejaculation, vaginal dryness, low libido, and dyspareunia.

277. Healthcare providers who treat sexual dysfunction enter into pharmacy partnership agreements with manufacturers of treatments targeting sexual dysfunction for their supply of medications that treat disorders falling into this category. A single healthcare provider may treat an array of sexual dysfunction disorders—rather than a single disorder by itself—in the above-listed categories, necessitating a pharmacy partnership in which the supplier manufactures treatments for more than just a single disorder.

278. Drugs and treatment formulated to address sexual dysfunction include, but are not limited to, the following drugs and treatments: Bi-Mix, Tri-Mix, Quad-Mix, cabergoline, estriol/estradiol medications and topical treatments, oxytocin medications, pseudoephedrine, sildenafil, tadalafil, testosterone treatments, and vardenafil.

279. Because consumers do not consider other medications to be reasonable substitutes for compounded treatments targeting sexual dysfunction given their varying characteristics, uses, and pricing structures, a small but significant increase in the price of these treatments would not cause consumers to switch to other treatments.

iv. The Market for Supply of Dermatology Medications and Treatments

280. Dermatology is the branch of medicine that deals with the diagnosis, treatment, and prevention of diseases, disorders, and conditions affecting the skin, hair, nails, and mucous

[58] *Sexual Dysfunction*, Cleveland Clinic, https://my.clevelandclinic.org/health/diseases/9121-sexual-dysfunction (last visited Mar. 22, 2025).

membranes. Healthcare providers who practice dermatology can address a wide range of skin-related conditions, from acne and eczema to skin cancer.

281. This market encompasses manufacturers—including compounders—of medications and treatments prescribed by a licensed healthcare provider in the practice of dermatology.

282. Healthcare providers engaged in the practice of dermatology enter into pharmacy partnership agreements for their supply of dermatology medications and treatments. Because providers do not often treat only a single dermatological condition or issue, they require access to pharmaceutical manufacturers offering a variety of medication and treatments formulated to treat dermatological conditions.

283. Dermatology medications and treatments include, but are not limited to, the following drugs and treatments: acne gels, anti-fungal medications, biotin capsules and injections, anti-aging gels, dermatitis creams, doxycycline, dutasteride, finasteride, hair-restoration and scalp treatments, melasma creams and gels, rosacea creams and gels, and prednisone.

284. Because consumers do not consider other medications or treatments to be reasonable substitutes for compounded treatments targeting dermatological conditions given their varying characteristics, uses, and pricing structures, a small but significant increase in the price of these treatments would not cause consumers to switch to other treatments.

v. The Market for Supply of Fertility Treatments

285. Fertility treatments aim to enhance reproductive health and increase chances of conception. The market of the supply of fertility treatments encompasses the manufacturing of

medications and treatments that aid with conception and pregnancy. Medication-based fertility treatments often include medications that help with hormones and ovulation.[59]

286. Healthcare providers who treat infertility conditions enter into pharmacy partnership agreements for their supply of fertility treatments. Because an individual healthcare provider may prescribe different fertility treatments to address infertility conditions depending on the patient, suppliers of fertility treatments often manufacture multiple, different fertility treatment medications.

287. Medication-based fertility treatments include, but are not limited to, the following drugs and treatments: cabergoline, clomiphene, enclomiphene, hydroxocobalamin, and progesterone.

288. Because consumers do not consider other medications or treatments to be reasonable substitutes for compounded treatments targeting infertility conditions given their varying characteristics, uses, and pricing structures, a small but significant increase in the price of these treatments would not cause consumers to switch to other treatments.

vi. The Market for the Supply of Mental Health Medications

289. Medications can be used to treat mental health disorders and conditions. The market for the supply of mental health medications includes drugs formulated to improve brain health, treat depression and trauma-related conditions, treat anxiety and anxiety-related conditions, and provide mood support.

290. Healthcare providers who treat mental health conditions enter into pharmacy partnership agreements for their supply of mental health medications. Because providers do not

[59] *Fertility Treatments*, Planned Parenthood, https://www.plannedparenthood.org/learn/pregnancy/fertility-treatments (last visited Mar. 22, 2025).

often treat only a single mental health condition or issue, they require access to pharmaceutical manufacturers offering a variety of medication and treatments formulated to treat various mental health conditions.

291. Medications formulated to treat mental health conditions include, but are not limited to, bupropion, ketamine (including nasal sprays, orally disintegrating tablets, and troches), fluoxetine, methylene, mirtazapine, modafinil, oxytocin, propranolol, sertraline, topiramate, trazadone, and zolpidem.

292. Because consumers do not consider other medications or treatments to be reasonable substitutes for compounded treatments targeting mental health conditions given their varying characteristics, uses, and pricing structures, a small but significant increase in the price of these treatments would not cause consumers to switch to other treatments.

vii. The Market for the Supply of Longevity and Anti-Aging Drugs and Therapies

293. Longevity and anti-aging drugs and therapies are those formulated for the purpose of slowing or reversing the aging process and/or to address age-related illnesses or problems connected to aging. The market for the supply of longevity and anti-aging drugs and therapeutics encompasses manufacturers who formulate and manufacture products formulated for the above-stated purposes.

294. Consumers interested in slowing or reversing the aging process and/or receiving pharmaceutical treatment to address age-related illnesses or problems connected to aging may seek care from healthcare providers who are authorized to prescribe such drugs and therapies. Healthcare providers, in turn, enter into partnership agreements with manufacturers of longevity and anti-aging drugs and therapeutics for their supply of products. Because providers do not often treat only one type of longevity or anti-aging condition or concern, they require access to

pharmaceutical manufacturers offering a variety of products formulated to treat longevity or anti-aging concerns.

295. Products formulated to slow or reverse the aging process and/or treat age-related illnesses or problems include, but are not limited to, alpha-lipoic acid; anti-aging gels and creams containing pharmaceutical ingredients such as niacin, niacinamide, sirolimus, ascorbic acid, azelaic acid, alpha lipoic acid, estriol, progesterone, and tretinoin; branched-chain amino acid (BCAA) injections; cholecalciferol (D3) injections and capsules; chromium picolinate; coenzyme; DHEA; cyanocobalamin; GHK-CU facial serums; glutathione; nicotinamide adenine dinucleotide (NAD+) (including creams, injections, and nasal sprays); methylene; modafinil; niacin IR/SR; omnitrope; pregnenolone; propranolol; rapamycin (sirolimus); resveratrol; selenium; norditropin; testosterone treatments; tretinoin; and zomacton.

296. Because consumers do not consider other products to be reasonable substitutes for compounded treatments targeting longevity and anti-aging concerns given their varying characteristics, uses, and pricing structures, a small but significant increase in the price of these treatments would not cause consumers to switch to other treatments.

E. The Geographic Market is the United States

297. The relevant geographic market is no larger than the United States. Pharmaceutical products are sold and regulated on a nationwide basis. Due to the importance of complying with the federal regulatory framework applicable to compounding products in the United States, a small, but significant, and non-transitory increase in the price of products compounded in the United States would not cause prescribing physicians and patients to substitute in significant numbers to other products or treatments that are not available in the United States.

F. LegitScript's Conduct Harms Interstate Commerce

298. The compounded products at issue in this case are sold and distributed in interstate commerce. LegitScript's unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

CAUSES OF ACTION

COUNT ONE: AGREEMENTS THAT UNREASONABLY RESTRAIN TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1, Texas Antitrust Act, Texas Business and Commercial Code § 15.05(a), New Jersey Antitrust Act, N.J.S.A. § 56:9-3

299. Plaintiff Empower incorporates by reference the foregoing paragraphs 1 through 298 of this Complaint as if fully set forth herein.

300. Defendant LegitScript and unnamed co-conspirators joined in a conscious commitment to a common scheme designed to achieve an unlawful objective—the suppression of competition through the delay and restraint of competition in the market for the manufacture and sale of compounded products and relevant product markets for products that may be compounded.

301. Defendant LegitScript and unnamed co-conspirators have committed overt acts, as described above, in furtherance of this unlawful, common scheme that together and individually have unreasonably, substantially, and unjustifiably restrained competition in the relevant markets and that have caused actual adverse market effects by delaying and restraining competition; depriving providers, clinics, and patients the benefits of price competition and lower prices; and by restraining output for compounded products, including compounded GLP-1 medications, semaglutide and tirzepatide.

302. As part of this overarching unlawful scheme to suppress competition, LegitScript has repeatedly violated the law by entering into anticompetitive agreements that have unreasonably and unjustifiably restrained competition, including at least:

A. exercising bias in its adoption and application of LegitScript's Healthcare Merchant Certification Standard 5 (the "Affiliates" rule) prohibiting applicants

for certification from being "affiliated" with a non-LegitScript certified pharmacy or outsourcing facility;

B. using its "Affiliates" rule to coerce Empower's customers to stop doing business with Empower, or to not enter into a business relationship with Empower, thereby restricting Empower's access to key customers and distribution channels needed to compete;

C. directly informing Empower's customers that, as a rule, a business relationship with Empower constitutes a barrier to certification;

D. arbitrarily imposing a six (6) month waiting period before Empower would be eligible to reapply for certification, allowing LegitScript to continue its unreasonable enforcement of its "Affiliates" rule against Empower;

E. arbitrarily imposing a rule prohibiting LegitScript-certified 503A pharmacies from sourcing products from 503B outsourcing facilities that are not LegitScript-certified despite lacking any authority to impose such a restriction and without the practical means to enforce the rule in an unbiased and non-discriminatory manner;

F. enforcing its "Affiliates" rule in an arbitrary and biased manner against Empower while allowing Empower's competitors to access customers and distribution channels despite apparent non-compliance with LegitScript's "Affiliates" rule;

G. on information and belief, allowing unidentified co-conspirators and competitors of Empower to exert undue influence over its Healthcare Merchant Certification process to deny Empower a LegitScript Healthcare Merchant

Certification and again, allowing LegitScript to continue to unreasonably enforce its "Affiliates" rule to restrain Empower from accessing key customers and distribution channels;

H. continuing to maintain and facilitate the agreement with providers, clinics, and other Empower customers to boycott and concertedly refuse to deal with Empower as a supplier of compounded products, including compounded GLP-1 medications; and

I. on information and belief, continuing to maintain and facilitate the agreement between providers, clinics, and other Empower customers to boycott and concertedly refuse to deal with Empower as a supplier of compounded products, including compounded GLP-1 medications, as a result of an agreement with and to the benefit of pharmaceutical manufacturers and telemedicine companies with whom LegitScript maintains close ties.

303. As detailed above, LegitScript has market and monopoly power in the market for certification of telemedicine providers, online pharmacies, 503A pharmacies, and 503B outsourcing facilities.

304. LegitScript has leveraged its market and monopoly power in the market for certification to unreasonably restrain trade in the market for the manufacture and sale of compounded products and relevant product markets for products that may be compounded.

305. By communicating its unreasonable rule prohibiting Empower's customers—clinics and providers who compete with one another—from working with Empower, LegitScript has instituted and enforced a group boycott and "concerted refusal to deal" of Empower by these customers. These agreements constitute unlawful concerted refusals to deal because two or more

unaffiliated entities have agreed not to deal with Empower as a result of LegitScript's coercion unjustifiably distorting the competitive process. LegitScript has participated in these unlawful concerted refusals to deal by facilitating the group boycott and informing Empower's customers that competing applicants and LegitScript-certified entities are likewise required to boycott Empower. These agreements also constitute unlawful group boycotts because they are designed to substantially foreclose Empower's access to key customers and necessary distribution channels.

306. This web of agreements to refuse to deal with Empower facilitated by LegitScript cannot be justified by any purportedly procompetitive purpose, such as to ensure the safety and quality of compounded products sold through clinics and providers, because LegitScript regularly certifies similarly situated compounding pharmacies with similar types of regulatory and compliance "issues" that LegitScript has identified as grounds for refusing to certify Empower. Moreover, LegitScript does not evenly enforce its "Affiliates" rule, leading to the conclusion that its purpose is to prevent some pharmacies and outsourcing facilities, such as Empower, from fully accessing the market. Additionally, LegitScript lacks any authority to regulate the pharmaceutical market and is without the practical ability to ensure unbiased and non-discriminatory regulation of the market.

307. Absent any procompetitive justification, clinics and providers' refusals to deal with Empower facilitated by LegitScript serve the anticompetitive purpose of cutting Empower off from the buyer market for compounded drugs.

308. Clinics and providers' refusals to deal with Empower facilitated by LegitScript also serve the anticompetitive purpose of reducing output in the market for compounded products by forcing clinics and providers to act against their own economic interest; by agreeing to refuse to

deal with Empower, clinics and providers are coerced into obtaining their supply of compounded products from compounding pharmacies that lack the ability to match Empower's operational volume which is significantly less cost effective and are therefore forced to pay higher prices than they would in a competitive market.

309. These concerted refusals to deal have unreasonably restrained trade and resulted in reduced price competition in the market for the manufacture and sale of compounded products and the relevant product markets. These concerted refusals to deal have further led to a substantial reduction in prescriber, pharmacy, and patient choice.

310. Defendants' conduct takes place in and restrains interstate commerce.

311. Defendants' conduct has had a substantial effect on intrastate commerce within the state of Texas.

COUNT TWO: TYING
VIOLATION OF SECTIONS 1 AND 2 OF THE SHERMAN ACT, 15 U.S.C. §§ 1, 2,
Texas Antitrust Act, Texas Business And Commercial Code § 15.05(c),
New Jersey Antitrust Act, N.J.S.A. § 56:9-3

312. Empower incorporates by reference the foregoing paragraphs 1 through 311 of this Complaint as if fully set forth herein.

313. LegitScript's agreements with customers that require them to purchase products from LegitScript-certified entities, or at least not to purchase compounded products from Empower, if they wish to purchase LegitScript's certification constitute unlawful tying arrangements.

314. These tying arrangements unreasonably restrain and substantially foreclose competition for the sale of compounded products.

315. LegitScript's certification, on the one hand, and compounded or branded products, on the other, are separate and distinct products.

316. LegitScript's market and monopoly power in the certification market gives it sufficient market power or control over the supply of advertising to online pharmacies to coerce those online pharmacies to purchase products only from LegitScript-certified entities and not from Empower, even when they would prefer not to do so and to purchase compounded products from Empower instead.

317. LegitScript's tying arrangements affect a significant volume of interstate commerce.

318. These tying arrangements increase LegitScript's monopoly power in the certification market by increasing the need to obtain LegitScript Certification in order to be able to compete on an even playing field against LegitScript-certified entities for sales and access to key customers and distribution channels needed to compete. LegitScript has an economic

interest in the tied sales of LegitScript-certified entities because the value of LegitScript's certification is increased when certified entities make more sales as a result of LegitScript's certification and when entities that are not certified are deprived of sales, thereby necessitating certification from LegitScript.

319. LegitScript's tying arrangements have harmed Empower's customers by depriving them of additional suppliers who compete for sales to those customers and have deprived those customers of access to additional output and sales, including during the national shortage of GLP-1s.

320. LegitScript's tying arrangements have caused Empower substantial damages as a direct and proximate cause of this unlawful conduct because LegitScript has unreasonably restrained Empower from competing for sales to customers seeking certification or that have become certified and has deprived Empower of critical sales channels to end customers and patients.

321. LegitScript's tying agreements are per se unlawful under the Sherman Act and state antitrust laws.

322. Alternatively, to the extent LegitScript is permitted to defend its tying agreements under a "quick look" and/or rule of reason standard, there is and was no legitimate, non-pretextual, procompetitive justification for LegitScript's tying restrictions capable of outweighing their anticompetitive effects. Even if there were some conceivable justification, LegitScript's restrictive rules and agreements are not reasonably necessary to achieve any such justification, which could have been achieved through less restrictive alternatives.

COUNT THREE:
Tortious Interference With Existing Contract Under Texas Law

323. Empower incorporates by reference the foregoing paragraphs 1 through 322 of this Complaint as if fully set forth herein.

324. Plaintiff Empower had in place contracts to sell and distribute compounded products to various providers listed in the paragraphs above.

325. LegitScript knew the customers above, as well as other customers yet to be identified through discovery, were doing business with, or had plans to do business with, Empower by way of purchasing compounded products. LegitScript's application requires applicants to disclose the pharmacies from which they expect to buy compounded products.

326. On information and belief, LegitScript also knew Plaintiff had entered into contracts with the customers above and/or their agents to sell compounded products.

327. On information and belief, LegitScript knew that interfering in these contractual relationships would cause injury to Empower.

328. LegitScript has intentionally, improperly, and without justification or excuse interfered with those contracts by informing Plaintiff's customers that they could not use Empower as a pharmacy if they wished to obtain a LegitScript Certification.

329. On information and belief, as a result of LegitScript's conduct, Empower's customers were coerced into no longer doing business with, or doing a smaller volume of business with, Empower, even though they wished to continue to source their supply of compounded products from Empower.

330. Moreover, LegitScript has also intentionally, improperly, and without justification or excuse interfered with Empower's contracts by making false and/or misleading and disparaging statements relating to Empower's business to at least the above-listed customers,

including, but not limited to, false and/or misleading and disparaging statements relating to the dispensing of drugs in violation of FDA rules and regulations.

331. As a result of LegitScript's intentional interference, customers have backed out of their agreements to purchase substantial quantities of compounded products from Empower and/or substantially decreased the quantities of their orders for compounded products from Empower.

332. Absent Defendant LegitScript's wrongful conduct, Plaintiff would have sold substantial quantities of compounded products to these and other customers. Plaintiff therefore has been harmed by LegitScript's wrongful conduct.

COUNT FOUR:
Tortious Interference With Prospective Business Relations Under Texas Law

333. Empower incorporates by reference the foregoing paragraphs 1 through 332 of this Complaint as if fully set forth herein.

334. As discussed above, Plaintiff had in place contracts to sell and distribute compounded GLP-1s to customers. However, Plaintiff further had a reasonable expectation of selling additional substantial volumes of compounded products to these customers and other similarly situated clinics and providers.

335. On information and belief, LegitScript reasonably knew that prospective customers would have entered into a business relationship with Empower. LegitScript's application requires applicants to disclose the pharmacies from which they expect to buy compounded products.

336. LegitScript interfered with such prospective business relationships by intentionally, improperly, and without justification or excuse interfering with those prospective business relationships by informing Plaintiff's prospective customers that they could not use Empower as a primary pharmacy if they wished to become LegitScript certified. LegitScript, however, arbitrarily and subjectively refused to certify Empower, further restricting Empower's ability to access key customers and the distribution channels necessary to compete in the market for the manufacture and sale of compounded products and the relevant product markets.

337. LegitScript represented to Empower's customers that its prohibition on LegitScript certified entities doing business with entities that are not LegitScript-certified, and specifically Empower, was a "policy." As a result of LegitScript's interference, Empower's customers were induced by LegitScript to unreasonably agree not to deal with Empower.

338. As stated above, these agreements constitute unlawful concerted refusals not to deal because two or more unaffiliated companies have unreasonably agreed to not deal with Empower as a supplier of compounded products.

339. LegitScript also intentionally, improperly, and without justification or excuse interfered with Empower's prospective business relations by making false and/or misleading and disparaging statements relating to Empower's business, including, but not limited to, false and/or misleading statements and disparaging statements relating to the dispensing of drugs in violation of FDA rules and regulations. As stated below, LegitScript's communications to Empower's prospective customers further constitutes business disparagement under Texas law.

340. On information and belief, LegitScript knew that interfering in these prospective relationships would cause injury to Empower.

341. Absent LegitScript's wrongful conduct, Plaintiffs would have sold substantial quantities of compounded products to prospective customers. Plaintiff therefore has suffered great economic harm as a proximate cause of LegitScript's actions.

COUNT FIVE:
Business Disparagement Under Texas Law

342. Empower incorporates by reference the foregoing paragraphs 1 through 341 of this Complaint as if fully set forth herein.

343. LegitScript has willfully misrepresented and/or omitted material facts, qualities, and characteristics relating to Empower's business, including, but not limited to, falsely communicating to Empower's customers that Empower is dispensing unlawful drugs; Empower is "unwilling" to come into compliance with LegitScript's standards; and that Empower has ongoing state boards of pharmacy violations that it has not resolved.

344. LegitScript has willfully misrepresented and/or omitted these material facts, qualities, and characteristics in communications to entities and/or their agents who are actual and potential customers of Plaintiff.

345. LegitScript has willfully continued making these claims in spite of its awareness of their falsity and/or potential to mislead.

346. On information and belief, LegitScript acted with the intent to interfere with Empower's economic interests by making such false and disparaging claims.

347. As a result of LegitScript's intentional interference, existing customers have backed out of their agreements to purchase substantial quantities of compounded products from Empower and/or substantially decreased the quantities of their orders for compounded products from Empower. LegitScript's actions have also deprived Plaintiff of substantial sales, threatened the loss of substantial future sales, and caused significant harm to Plaintiff's goodwill and reputation, further hurting Plaintiff's ability to compete for future sales.

348. Absent LegitScript's wrongful conduct, Plaintiff would have sold substantial quantities of compounded products to actual and prospective customers. Therefore, Plaintiff has been harmed by LegitScript's wrongful conduct.

COUNT SIX:
Texas Common Law Unfair Competition

349. Empower incorporates by reference the foregoing paragraphs 1 through 348 of this Complaint as if fully set forth herein.

350. LegitScript has interfered with Empower's business relations by confronting Empower's customers and prospective customers with an unjustified and unreasonable "policy" that prevents such customers from engaging Empower as their supplier of compounded products because it lacks a LegitScript Certification.

351. LegitScript has also arbitrarily and subjectively denied Empower's applications for a Healthcare Merchant Certification.

352. LegitScript's interference with Empower's business relations has induced Empower's existing and prospective customers to unreasonably agree to refuse to deal with Empower as their supplier of compounded products.

353. On information and belief, LegitScript's interference with Empower's business relations has caused customers and prospective customers to unreasonably agree to refuse to deal with Empower as their supplier of compounded products.

354. Based on information and belief, unidentified co-conspirators have participated in LegitScript's unlawful inducement of providers and clients' unreasonable refusal to deal with Empower by exerting pressure on LegitScript to (a) refuse to grant Empower a Healthcare Merchant Certification and/or (b) enforce an unreasonable and unjustifiable "policy" prohibiting LegitScript-certified entities from doing business with non-LegitScript certified entities.

355. LegitScript's conduct has unreasonably restrained trade and resulted in reduced price competition in the market for compounded products; a substantial reduction in prescriber,

pharmacy, and patient choice; and a substantial reduction in output in the market for compounded products.

356. Accordingly, the anticompetitive conduct alleged herein also constitutes a violation of the common law of Texas which prohibits unlawful acts by LegitScript that interfere with Plaintiff's ability to conduct its business.

DEMAND FOR JURY TRIAL

357. Empower hereby demands a jury trial on all of its claims.

PRAYER FOR RELIEF

358. Empower respectfully prays for the following relief:

359. Pursuant to 28 U.S.C. § 2201, a declaration that LegitScript's agreements with applicants and certified entities to abide by LegitScript's "Affiliates" rule prohibiting them from purchasing from Empower are unreasonable and unenforceable restraints of trade that violate Section 1 of the Sherman Act, 15 U.S.C. § 1, the Texas Business & Commercial Code §§ 15.01-15.52, and the New Jersey Antitrust Act, N.J.S.A. §§ 56:9-3, 9-4(a);

360. Pursuant to 28 U.S.C. § 2201, a declaration that LegitScript has unlawfully tied the sale of its Healthcare Merchant Certification to the sale of products sold by LegitScript certified entities, in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, the Texas Business & Commercial Code §§ 15.01-15.52, and the New Jersey Antitrust Act, N.J.S.A. §§ 56:9-3, 9-4(a);

361. Pursuant to 28 U.S.C. § 2201, a declaration that LegitScript's unreasonably restrictive "Affiliates" rule is null and void and cannot be enforced against LegitScript-certified entities, applicants, or other parties;

362. Pursuant to 28 U.S.C. § 2201, a declaration that LegitScript has commercially disparaged Empower;

363. Pursuant to 15 U.S.C. § 15, compensatory and trebled damages expected to exceed $100 million, and attorneys' fees and costs, resulting from Defendants' violations of the Sherman Act, the Texas Business & Commercial Code §§ 15.01-15.52 and New Jersey Antitrust Act, N.J.S.A. §§ 56:9-1-19;

364. Pursuant to 15 U.S.C. § 26, permanent injunctive relief preventing LegitScript from continuing the unlawful acts in violation of the Sherman Act, the Clayton Act, the Texas Business & Commercial Code §§ 15.01-15.52, the New Jersey Antitrust Act, and common law;

365. Pursuant to 15 U.S.C. § 26, permanent injunctive relief preventing and restraining LegitScript from tying the sale of any certification to products supplied by LegitScript-certified or other entities;

366. Pursuant to 15 U.S.C. § 26, permanent injunctive relief preventing and restraining LegitScript from foreclosing Empower's access to the relevant markets, customers, distribution channels, or other competitively significant relationships;

367. Pursuant to 15 U.S.C. § 26, permanent injunctive relief prohibiting LegitScript from applying its certification standards to Empower in a biased and discriminatory manner;

368. Pursuant to 28 U.S.C. § 2201, a declaration that LegitScript tortiously interfered with Empower's contracts for the sale of compounded products;

369. Pursuant to 28 U.S.C. § 2201, a declaration that LegitScript tortiously interfered with Empower's prospective economic advantage to be derived from expected customer relationships and an expected supply arrangements for compounded products and treatments;

370. Pursuant to 28 U.S.C. § 2202, such further relief as may be necessary or proper based upon this Court's declaratory judgments;

371. Pre-judgment and post-judgment interest at the maximum legal rate;

372. Compensatory damages, treble damages, attorneys' fees, and costs, including expenses for discovery and document productions pursuant to the New Jersey Antitrust Act, N.J.S.A. §§ 56:9-12; and

373. Such other relief as this Court may deem just and proper.

Dated: March 26, 2025

Respectfully submitted,

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